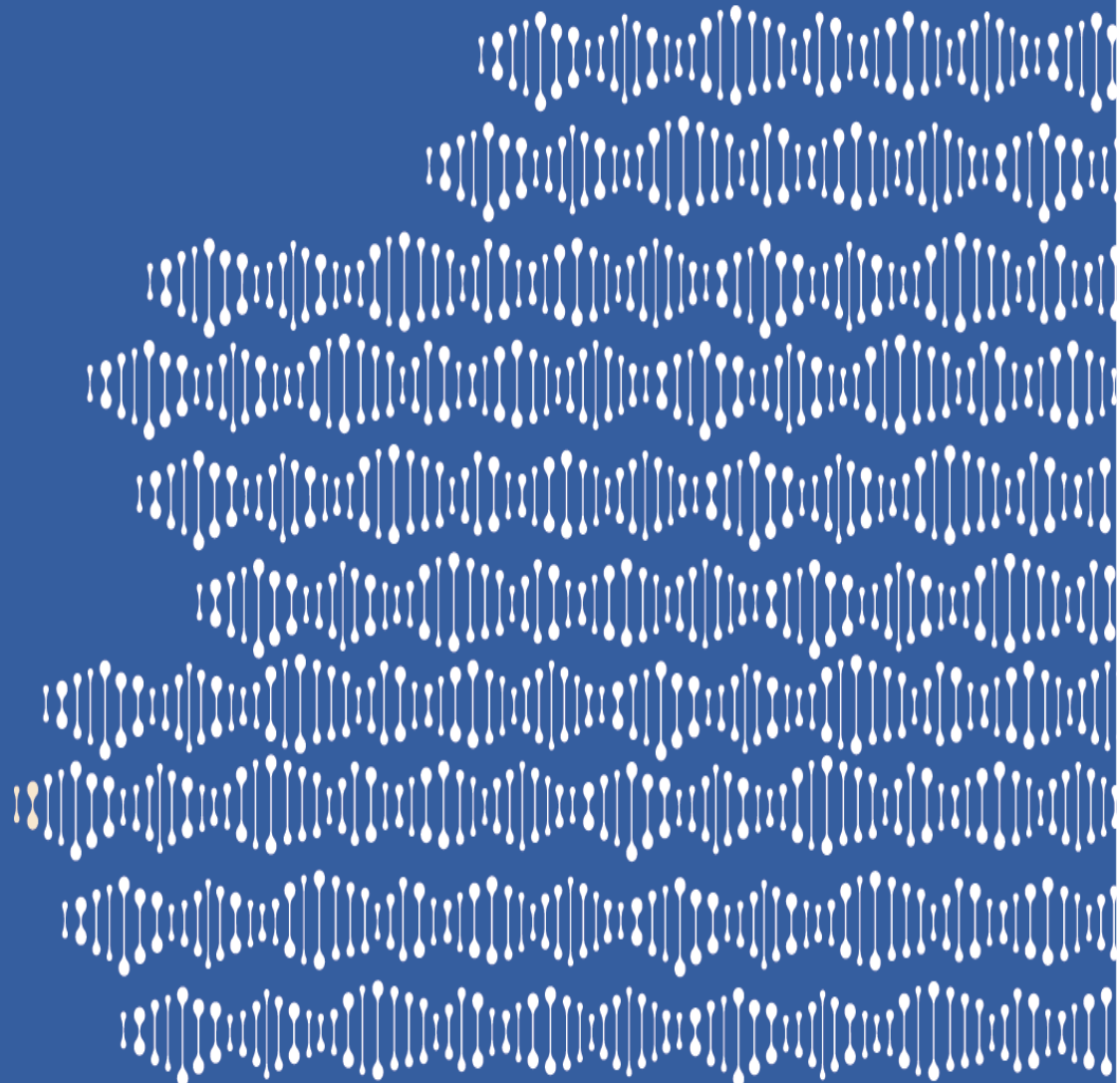




CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

Oversight Committee Meeting

May 19, 2021





CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

Summary Overview of the May 19, 2021, Oversight Committee Meeting

This summary provides an overview of major agenda items and background on key issues for Committee consideration at the May 19, 2021, Oversight Committee meeting.

Grantee Presentations

John P. Cooke, M.D., Ph.D., Chair, Department of Cardiovascular Sciences at the Houston Methodist Research Institute, Director of the Center for Cardiovascular Regeneration, and Medical Director of the CPRIT-supported RNA Therapeutics Core, will present an update on his CPRIT-funded projects.

CEO Report

Wayne Roberts will present the CEO's report and address issues including COVID-19, personnel, FY 2021 grant funds available, the legislative session, the Chief Scientific Officer search process, and other topics.

Chief Compliance Officer Report

Vince Burgess will report on the status of required grantee reports, financial status report reviews, desk reviews, site visits, annual compliance attestation, audit tracking, and training. He will also certify that the proposed academic research and prevention awards complied with statutory and administrative rule requirements.

Chief Scientific Officer Report and Grant Award Recommendations

Dr. Jim Willson will provide an update on the academic research program, including proposed fiscal year 2022 requests for applications, and present the Program Integration Committee's (PIC) recruitment and training award recommendations.

CPRIT does not publicly disclose information related to the academic research grant applications recommended for funding until the Oversight Committee meeting. The information is available to board members through a secure electronic portal.

Chief Prevention Officer Report and Grant Award Recommendations

Ramona Magid will update the Oversight Committee on the on the agency's prevention program and present the PIC's prevention award recommendations.

CPRIT does not publicly disclose information related to the prevention grant applications recommended for funding until the Oversight Committee meeting. The information is available to board members through a secure electronic portal.

Chief Product Development Officer Report

Dr. Cindy WalkerPeach will provide an update on the product development program.

Internal Auditor Report

Weaver and Tidwell, CPRIT's internal auditor, has provided an internal audit update.

Scientific Research and Prevention Programs Committee Appointments

Mr. Roberts provisionally appointed three new members to CPRIT's Scientific Research and Prevention Programs Committees. CPRIT's statute requires the Oversight Committee to approve the CEO's recommendation before the appointments are final. CPRIT has provided the appointees' biographical sketches for the Oversight Committee's consideration.

Advisory Committees

Four of the Oversight Committee's five advisory committees will present annual reports and answer Oversight Committee member's questions. (The Clinical Trials Advisory Committee will present their report at a future meeting.) In addition to the annual reports, Mr. Roberts will discuss the new Geographic Diversity Advisory Committee and Presiding Officer Dee Margo's appointments to this new committee.

Proposed Amendments to 25 TAC Chapters 703

Cameron Eckel will present the final order for amendments to Chapter 703 that the Oversight Committee provisionally approved at its meeting in November. She will also present two proposed changes to Chapters 702 and 703 administrative rules for Oversight Committee consideration and approval to publish in the *Texas Register*.

Chief Operating Officer Report

Heidi McConnell will provide the operating budget, performance measures, and debt issuance history for the second quarter of fiscal year 2021.

Contract Approval

Ms. McConnell will present staff's recommendation regarding a proposed contract for grant management support services.

Fiscal Year 2022 Request for Financing Authorization

Ms. McConnell will discuss staff's recommendation to approve a resolution requesting the Texas Public Finance Authority to issue debt on behalf of CPRIT for fiscal year 2022.

Communications Update

Chris Cutrone will update the Oversight Committee on CPRIT's communication activities, including coverage of the agency and grantees in earned media, digital media, and social media during February - May.



CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

Oversight Committee Meeting Agenda

May 19, 2021
9:00 a.m.

This Meeting Will Be Conducted by Videoconference and Telephonically

In accordance with Texas Government Code Section 418.016, Governor Abbott has suspended various provisions that require government officials and members of the public to be physically present at a specified meeting location.

Members of the public may connect to the meeting by going to the URL:
: <https://www.zoomgov.com/j/1613758015?pwd=ZHZKcll2NUV4MEdQVnBCSlVtd1NJdz09>

The public may also join via telephone audio only using the following:
US: +1 669 254 5252 or +1 646 828 7666 or +1 551 285 1373 and entering the **Webinar ID of 161 375 8015** when prompted.

A recording of the meeting will be available after the meeting on CPRIT's public website. CPRIT will provide an electronic copy of the agenda packet at <https://cprit.texas.gov/oversight-committee/meetings/> by May 17.

A member of the public wishing to comment during the meeting must contact Melanie Cleveland (mcleveland@cprit.texas.gov) at least 30 minutes prior to the posted meeting start time. When the Oversight Committee reaches the "Public Comment" agenda item, the Chair will recognize each person requesting to provide public comment by name. The Chair may limit the amount of time a member of the public may speak. CPRIT cannot guarantee that an individual contacting Ms. Cleveland less than 30 minutes before the posted start time may provide public comment.

The Oversight Committee may discuss or act on any item on this agenda, and as authorized by the Texas Open Meetings Act, Texas Government Code Section 551.001 et seq., may meet in closed session concerning any purpose permitted by the Act.

1. Call to Order
2. Roll Call/Excused Absences
3. Adoption of Minutes from the February 17, 2021, meeting Tab 1
4. Public Comment
5. Grantee Presentations Tab 2
6. Chief Executive Officer Report Tab 3
7. Chief Compliance Officer Report and Compliance Certification of Grant Award Process Tab 4
8. Chief Scientific Officer Report Tab 5
 - Grant Award Recommendations
 - FY 2022 Requests for Applications

- | | |
|--|--------|
| 9. Chief Prevention Officer Report | Tab 6 |
| • Grant Award Recommendations | |
| 10. Chief Product Development Officer Report | Tab 7 |
| 11. Internal Auditor Report | Tab 8 |
| 12. Scientific Research and Prevention Program Committee Appointments | Tab 9 |
| 13. Advisory Committees | Tab 10 |
| • Geographic Diversity Advisory Committee | |
| • Advisory Committee Appointments | |
| • University Advisory Committee Annual Report | |
| • Product Development Advisory Committee Annual Report | |
| • Prevention Advisory Committee Annual Report | |
| • Advisory Committee on Childhood Cancer Annual Report | |
| 14. Amendments to 25 T.A.C. Chapters 702 and 703 | Tab 11 |
| • Final Order Approving Amendments to Chapters 702 and 703 | |
| • Proposed Amendment to Chapter 703 | |
| 15. Chief Operating Officer Report | Tab 12 |
| 16. Contract Approvals | Tab 13 |
| • Grant Management Support Services | |
| 17. Fiscal Year 2022 Bond Issuance Resolution | Tab 14 |
| 18. Communications Report | Tab 15 |
| 19. Acceptance of Gift pursuant to T.A.C. § 702.7 | |
| 20. Subcommittee Business | |
| 21. Compliance Investigation Pursuant to Health & Safety Code § 102.2631 | |
| 22. Consultation with General Counsel | |
| 23. Future Meeting Dates and Agenda Items | |
| 24. Adjourn | |



CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

**Oversight Committee Meeting Minutes
February 17, 2021**

NOTE: CPRIT conducted this meeting by videoconference in accordance with Governor Abbott's suspension of various provisions requiring government officials to be physically present at a specified meeting location. Unless the information is confidential, the reports, presentations, and grant award information referenced in the minutes are available in the "Oversight Committee Board Packet" section for the corresponding meeting date at <http://ocmeetings.cprit.texas.gov>.

Call to Order – Agenda Item 1

With a quorum present, Presiding Officer Dee Margo called the meeting to order at 9:01 a.m.

Roll Call/Excused Absences – Agenda Item 2

Committee Members Present

David Cummings, M.D. (joined the meeting at 9:50, present until 10:35)

Ambrosio Hernandez, M.D.

Donald (Dee) Margo

Will Montgomery

Mahendra Patel, M.D. (joined the meeting at 9:06)

Cindy Barberio Payne

Bill Rice, M.D.

Craig Rosenfeld, M.D.

Adoption of Minutes from the November 18, 2020 Meeting – Agenda Item 3 – Tab 1

MOTION:

On a motion by Mr. Montgomery and seconded by Dr. Rice, the Oversight Committee unanimously voted to approve the minutes of the November 18, 2020, Oversight Committee meeting as presented.

Public Comment – Agenda Item 4

No member of the public requested to address the Oversight Committee.

Grantee Presentation – Agenda Item 5, Tab 2

Presiding Officer Margo recognized Chief Prevention Officer Ramona Magid. Ms. Magid introduced Dr. Abbey Berenson, professor, Departments of Obstetrics & Gynecology and Pediatrics, Director, Center for Interdisciplinary Research in Women's Health, and The Ruth Hartgraves MD Chair in Obstetrics & Gynecology at The University of Texas Medical Branch at Galveston. Dr. Berenson gave a brief presentation about her work on CPRIT-funded prevention projects from 2012 through 2021.

Following her presentation, an Oversight Committee member asked Dr. Berenson if she was able to predict the number of cancers averted because of these projects. Dr. Berenson explained that she would need to do many calculations to determine the number of cancers averted because the vaccine prevents six different types of cancer. The number is significant, particularly if one counts the number of women who will not need biopsies or LEEP procedures because of an abnormal Pap smear.

An Oversight Committee member asked if Dr. Berenson considered working with health districts. Dr. Berenson responded that the pandemic delayed work with the districts, but that the team will look to partnering in the future.

In response to an Oversight Committee member's request for Dr. Berenson to elaborate on people's resistance to vaccines in East Texas, she explained that it is not certain if the resistance is due to social media or another cause; when asked, patients usually indicate that they do not feel the vaccines are safe.

An Oversight Committee member inquired about interest in requiring HPV vaccination for school-aged children. Dr. Berenson responded that a mandate in Texas is unlikely soon; other states have tried to mandate the HPV vaccine for school attendance and, in most cases, have not been successful.

An Oversight Committee member asked Ms. Magid if CPRIT was implementing programs like Dr. Berenson's projects in other areas of Texas. Ms. Magid responded that CPRIT is currently funding several other prevention projects related to HPV vaccination throughout the state.

Presiding Officer Margo recognized Chief Product Development Officer Cindy WalkerPeach. Dr. WalkerPeach introduced Dr. Michael Curran, founder of CPRIT grantee ImmunoGenesis and James Barlow, ImmunoGenesis CEO. Dr. Curran and Mr. Barlow gave a presentation about the progress of their company's CPRIT-funded project.

Chief Executive Officer Report – Agenda Item 6, Tab 3

Presiding Officer Margo recognized Mr. Roberts to present the Chief Executive Officer's Report. Mr. Roberts informed the board that CPRIT has approximately \$250 million funds remaining in fiscal year 2021 appropriations. Mr. Roberts introduced Ms. Tracey Davies, who will begin working at CPRIT on March 1 as Chief Strategic Initiatives and Intellectual Property Officer.

As part of his legislative update, Mr. Roberts explained the increased charge for the Statewide Cost Allocation Plan (SWCAP) assessed to agencies for using services at the State Auditor's Office, Comptroller, and Office of Attorney General.

Mr. Roberts updated the Oversight Committee on the Chief Scientific Officer search effort. He also provided his annual CEO report on the continued progress of CPRIT's three programs, as required by Texas Health & Safety Code § 102.260(c).

Mr. Roberts concluded his report by highlighting CPRIT's fiscal year 2020 Annual Report, which is available exclusively online for the first time. Mr. Roberts complimented the work of Therry Simien, Shannon Cusick, Chris Cutrone and Kristen Doyle on the new annual report.

Before the Oversight Committee took up the next agenda item, Ms. Doyle announced that Dr. Cummings left the meeting due to inclement weather conditions affecting his wireless connectivity.

Chief Compliance Officer Report and Compliance Certification for the Proposed Grant Awards – Agenda Item 7, Tab 4

Presiding Officer Margo recognized Chief Compliance Officer Vince Burgess to present the Compliance Report and Compliance Certification of Grant Award Process. Mr. Burgess updated members on the compliance program activities for the past quarter. He highlighted the compliance program's match expenditures review. CPRIT requires academic research and product development research grantees to provide a detailed match expenditure report annually; the compliance team is reviewing all match expenditure reports. It processed three grantee reviews in January, with ten completed in total - about 19 million dollars in match expenses.

With no questions on compliance activities, Mr. Burgess moved on to certify the review process for the proposed academic research awards presented for the Oversight Committee's consideration, explaining that the review complied with all applicable state and agency requirements. He noted that he included his written certification in the award book at page 21.

Chief Scientific Officer Report and Grant Award Recommendations – Agenda Item 8, Tab 5

Presiding Officer Margo recognized Chief Scientific Officer Dr. Jim Willson to present the academic research program update and award recommendations. Dr. Willson referred members to page 5-1 of the meeting book and provided an overview of the Research Training Award RFA and the number of applications submitted for the 21.1 RFA Cycle. He will present the Scientific Review Council (SRC) recommendations regarding the training awards to the Program Integration Committee (PIC) and Oversight Committee in May.

Looking ahead to future review cycles, Dr. Willson noted that CPRIT will convene virtual peer review meetings in late May to evaluate the second cycle of research applications submitted for fiscal year 2021 grant awards. The Oversight Committee will consider the SRC's recommendations in August. Peer review panels will meet in October to evaluate applications submitted for the first grant award cycle in fiscal year 2022.

Dr. Willson referred members to page 6 of the award book and presented the recruitment slate recommended by the SRC and the PIC for fiscal year 2021 recruitment cycles 21.4 and 21.5.

Recommendations for Recruitment Cycles FY 21.4 and FY 21.5

Rank	App. ID	Award	Candidate	Organization	Budget	Score
1	RR210023	REI	Alex Mazin, Ph.D.	The University of Texas Health Science Center at San Antonio	\$6,000,000	1.0
2	RR210009	REI	Othon Iliopoulod, M.D.	Baylor College of Medicine	\$6,000,000	2.4

REI- Recruitment of Established Investigators

Conflict of Interest Notification

Presiding Officer Margo noted for the record that no Oversight Committee members reported a conflict of interest with any proposed academic research awards.

Approval Process – Academic Research Awards

Presiding Officer Margo called for a vote on the recruitment award recommendations.

MOTION:

On a motion made by Dr. Rosenfeld and seconded by Dr. Patel, the Oversight Committee members voted unanimously to approve the PIC's recommendations for the recruitment award slate.

MOTION:

On a motion made by Mr. Montgomery and seconded by Dr. Patel, the Oversight Committee members voted unanimously to approve the delegation of contract negotiation authority to CPRIT's CEO and staff and authorized the CEO to sign the contracts on behalf of CPRIT.

Chief Prevention Officer Report – Agenda Item 9, Tab 6

Presiding Officer Margo recognized Chief Prevention Officer Ramona Magid to update the Oversight Committee on the prevention program. Ms. Magid reported on prevention program activities and gave a brief update on the impact of the COVID-19 pandemic on CPRIT-funded prevention projects. Oversight Committee members discussed how best to spread the word to Texans about the importance of regular preventative screenings and vaccinations.

Ms. Magid presented the fiscal year 2022 RFA release schedule and timelines for consideration. The proposed RFAs in the schedule include Dissemination of CPRIT-Funded Cancer Control Interventions, Evidence-Based Cancer Prevention Services, Expansion of Cancer Prevention Services to Rural and Medically Underserved Populations, Prevention Program Assessment, and Tobacco Control and Lung Cancer Screening.

MOTION:

On a motion made by Dr. Patel and seconded by Mr. Montgomery, the Oversight Committee unanimously voted to approve the Prevention Program's plan for proposed RFAs for fiscal year 2022.

Chief Product Development Officer Report – Agenda Item 10, Tab 7

Presiding Officer Margo recognized Chief Product Development Officer Cindy WalkerPeach, Ph.D., to present the Product Development Research update. Dr. WalkerPeach reported on the status of the applications under review in the current 21.1 cycle. Dr. WalkerPeach finished her report with a presentation of the proposed review timeline and three Product Development Research RFAs for the first and second cycles of fiscal year 2022.

MOTION:

On a motion made by Dr. Patel and seconded by Mr. Montgomery, the Oversight Committee unanimously voted to approve the proposed timeline and Product Development Research RFAs for the first and second cycles of fiscal year 2022.

Internal Auditor Report – Agenda Item 11, Tab 8

Presiding Officer Margo recognized Alyssa Martin, a partner with Weaver & Tidwell, to review the fiscal year 2021 internal audits and the projected schedule of internal audit activities. She directed the members to the chart on page 8-3 of the meeting packet, which provides an overview of internal audit activities since 2015. Ms. Martin noted that CPRIT will address the four open items in the follow-up procedure audits.

Mr. Montgomery asked about the outstanding findings that the communications follow-up procedures audit was to evaluate in fiscal year 2020. Ms. Martin responded that CPRIT and the internal auditors postponed the follow-up procedures audit until fiscal year 2021 because of COVID-19 scheduling and travel issues.

Scientific Research and Prevention Program Committee Appointments – Item 12, Tab 9

Presiding Officer Margo recognized Mr. Roberts to present his three appointments to the Scientific Research and Prevention Program Committees (Dr. Martin Pomper, Dr. Trey Ideker and Dr. Joya Delgado Harris) and the Presiding Officer's appointment to the Prevention Advisory Committee.

MOTION:

On a motion made by Dr. Rice and seconded by Dr. Patel, the Oversight Committee unanimously voted to approve Mr. Roberts' three appointments to CPRIT's Scientific Research and Prevention Program Committees.

Amendments to 25 T.A.C. Chapters 702 and 703 – Item 13, Tab 10

Presiding Officer Margo recognized CPRIT assistant general counsel Cameron Eckel to explain proposed rule changes to Chapter 703. Ms. Eckel presented a final order approving the amendments to T.A.C. §§703.3 and 703.26, which the Oversight Committee initially approved for publication in the *Texas Register* at the November 2020 Oversight Committee meeting.

She also addressed preliminary approval for the proposed amendments to T.A.C. §§ 702.19 and 703.10, which CPRIT will publish in the *Texas Register* for public comments and bring back to the Oversight Committee for final approval in May.

MOTION:

On a motion made by Dr. Rice and seconded by Mr. Montgomery, the Oversight Committee unanimously voted to approve the final order adopting rule changes to the Texas Administrative Code Chapter 703 and to approve the publication of the proposed changes to Chapters 702 and 703 in the Texas Register.

Chief Operating Officer Report – Agenda Item 14, Tab 11

Presiding Officer Margo recognized Chief Operating Officer Heidi McConnell to provide her report. Ms. McConnell updated the board regarding the State Auditor's Office (SAO) audit, explaining that the SAO is still in its planning phase after completing interviews with various CPRIT staff and two members of the Oversight Committee. The SAO plans to issue an audit report in July.

In response to a question from Dr. Rosenfeld about issues that the audit team has already identified, Ms. McConnell clarified that the audit team is in the information gathering phase of the audit and has not identified any issues with CPRIT's grantmaking processes.

Search Firm Contract Approval – Agenda Item 15, Tab 12

Presiding Officer Margo recognized Ms. McConnell to present the staff recommendation for a search firm contract. She explained that staff recommends that the Oversight Committee approve a contract with Spencer Stuart to conduct the search for CPRIT's new Chief Scientific Officer (CSO). Ms. McConnell noted that CPRIT has worked with Spencer Stuart in past searches, so staff has firsthand knowledge of the firm's capabilities.

In response to a question from Mr. Montgomery about ensuring that the cancer research community is aware of the search for a new CSO, Mr. Roberts responded that he has reached out to contacts at academic and private research institutions to notify them of the CSO search. CPRIT and the search firm will continue and expand these efforts.

Dr. Hernandez inquired about the payment of the search firm's out-of-pocket expenses under the contract. Ms. McConnell clarified that out-of-pocket expenses are in addition to the base contract cost; however, prior to the firm incurring any out-of-pocket expense it must submit a written reimbursement request and CPRIT must approve the request in writing.

MOTION:

On a motion made by Dr. Hernandez and seconded by Mr. Montgomery, the Oversight Committee unanimously voted to approve the contract with Spencer Stuart.

Communications Report – Agenda Item 16, Tab 13

Presiding Officer Margo recognized Senior Communications Specialist Chris Cutrone to present the communications update. Mr. Cutrone presented CPRIT's media coverage over the last quarter, noting that Innovation Map out of Houston has covered several CPRIT grantees and Texas Tech University Health Sciences Center received television coverage on a Core Facility Award.

Subcommittee Business – Agenda Item 17

Compliance Investigation Pursuant to Health & Safety Code § 102.2631 – Agenda Item 18

Consultation with General Counsel – Agenda Item 19

The Oversight Committee did not take up these items.

Future Meeting Dates and Agenda Items – Agenda Item 20

The next regular Oversight Committee meeting will convene on May 19, 2021. CPRIT expects to hold the May meeting by videoconference.

Adjournment – Agenda Item 21

MOTION:

There being no further business, the Oversight Committee unanimously voted to approve a motion to adjourn made by Presiding Officer Margo and seconded by Mr. Montgomery.

Meeting adjourned at 11:29 a.m.

Signature

Date



JOHN P COOKE MD PHD

Joseph C. "Rusty" Walter and Carole Walter Looke Presidential Distinguished Chair
in Cardiovascular Disease Research

Houston Methodist Research Institute

Academic background. Dr. Cooke trained in Cardiovascular Medicine at the Mayo Clinic and obtained a Ph.D. in Physiology there. Thereafter he was recruited to Harvard Medical School as an Assistant Professor of Medicine. Subsequently, he was recruited to Stanford University to develop a Vascular Medicine program and was Professor in the Division of Cardiovascular Medicine at Stanford University School of Medicine, and Associate Director of the Stanford Cardiovascular Institute until his recruitment to the Houston Methodist Research Institute (HMRI) in July 2013. There, he is Professor and Chair of the Department of Cardiovascular Sciences; Director of the Center for Cardiovascular Regeneration; Medical Director of the Center for RNA Therapeutics; and Chief Translational Science officer for the Houston Methodist Research Institute.

Research Program. Dr. Cooke founded the RNA Therapeutics program at HMRI in 2013. The RNA Therapeutics program is a unique hybrid of academic pursuits and product development. He and his team have developed proprietary methods for the synthesis, purification, validation, lyophilization, and delivery of mRNA. Their manufacturing processes have been licensed by an experienced manufacturer of nucleic acid therapies, VGXI Inc. The RNA Therapeutics team at HMRI makes RNA constructs for investigators world-wide, as well as clinical grade mRNA for GLP studies and clinical trials. Furthermore, faculty in Nanomedicine work closely with the RNA Therapeutics team to develop delivery strategies for topical and systemic delivery of RNA. The HMRI has a full spectrum of comparative medicine services for GLP testing of mRNA therapies, as well as a first-in-man clinical trials unit. With our industry partner VGXI, we provide a full assembly line for RNA Therapeutics from pre-clinical to Phase III clinical trials.

Dr. Cooke has explored the use of mRNA encoding human telomerase in Hutchison Gilford Progeria Syndrome, and other RNA-enhanced cell therapies. Recent insights from the laboratory have clarified the role of innate immune signaling in nuclear reprogramming to pluripotency and therapeutic transdifferentiation using mRNA. His translational research program is focused on regenerative medicine and is funded by grants from the National Institutes of Health, the American Heart Association, Cancer Prevention Research Institute of Texas, Progeria Research Foundation and industry. Dr. Cooke has published over 550 research papers, reviews and patents with over 33,000 citations; h index = 97 (Scopus 3-11-21). For his success in generating and commercializing IP, he was named as an Outstanding Inventor of 2015 by the Office of Technology Transfer at Stanford University, and elected to the National Academy of Inventors in 2019; and received the Mayo Clinic Distinguished Alumni Award in 2020.



CANCER PREVENTION & RESEARCH
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CPRIT RNA THERAPEUTICS CORE

Presented By:

John P. Cooke, MD, PhD

Medical Director, RNA Therapeutics Program

Professor and Chair, Department of Cardiovascular Sciences

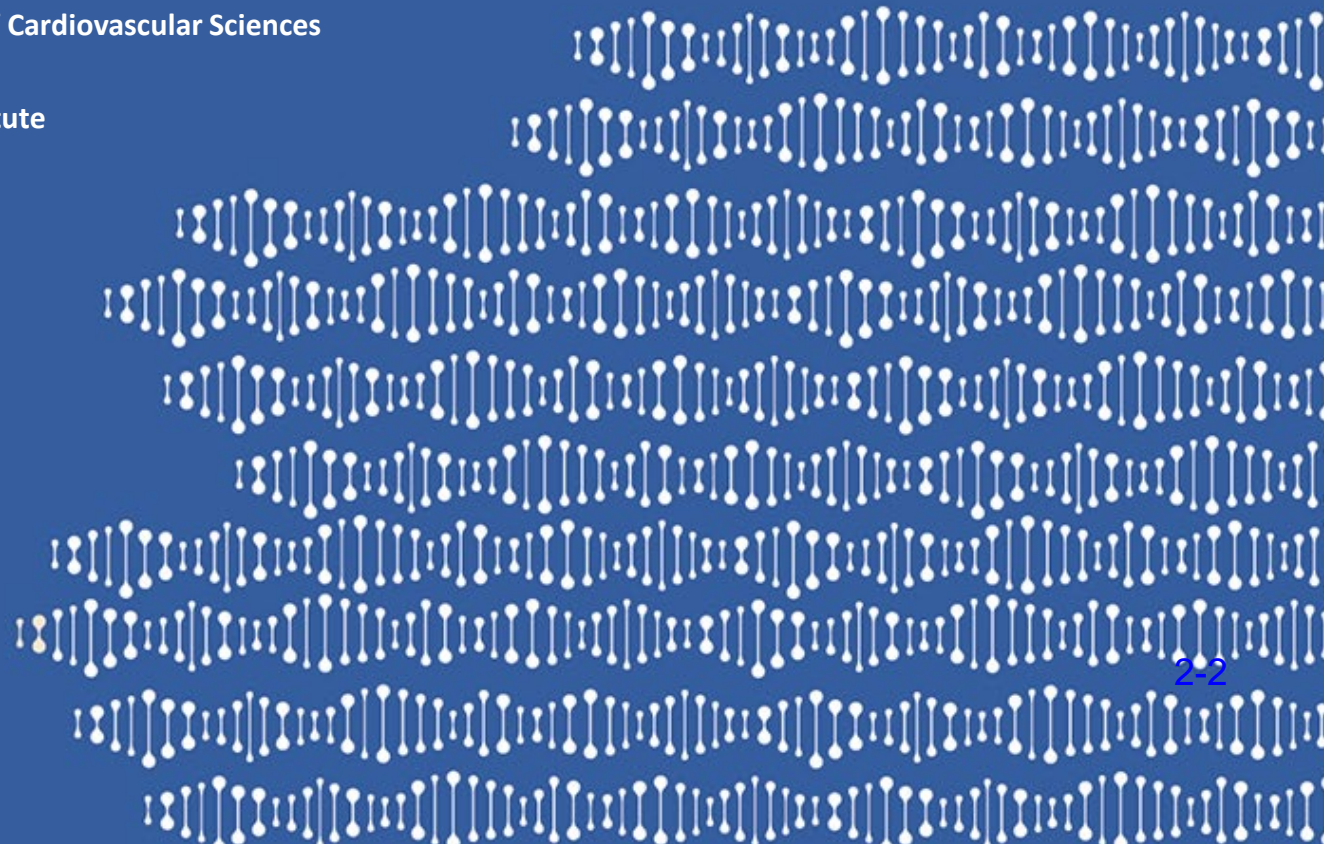
Chief Translational Office

Houston Methodist Academic Institute

Presented To:

CPRIT Oversight Committee

May 19, 2021





CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

RFA R-15-CFSA-2

Core Facilities Support Awards

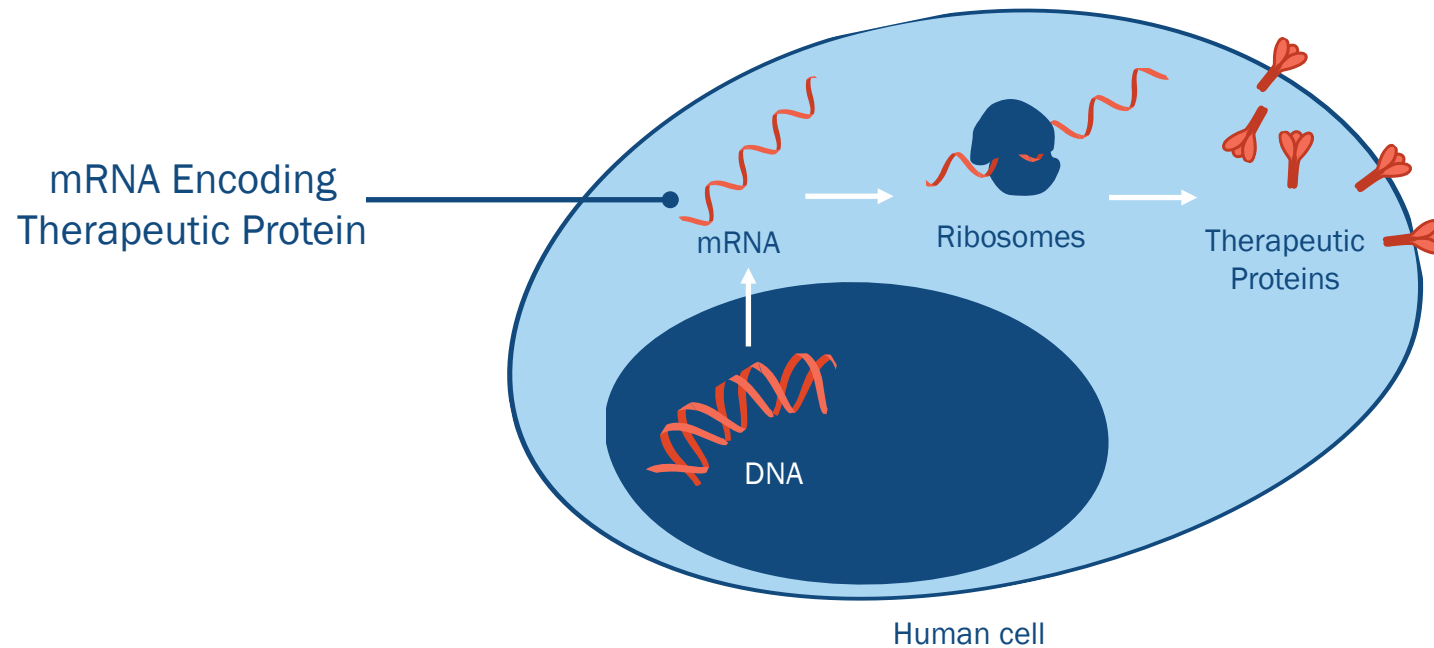
November 17, 2014

2-3

- “The CPRIT RNA Core will address an unmet need for both cancer biologists and for oncology trialists in Texas. “
- “Recent advances in the generation and delivery of **mRNAs**...now provides great opportunities for.... cancer biology, as well as for novel oncotherapeutics.”

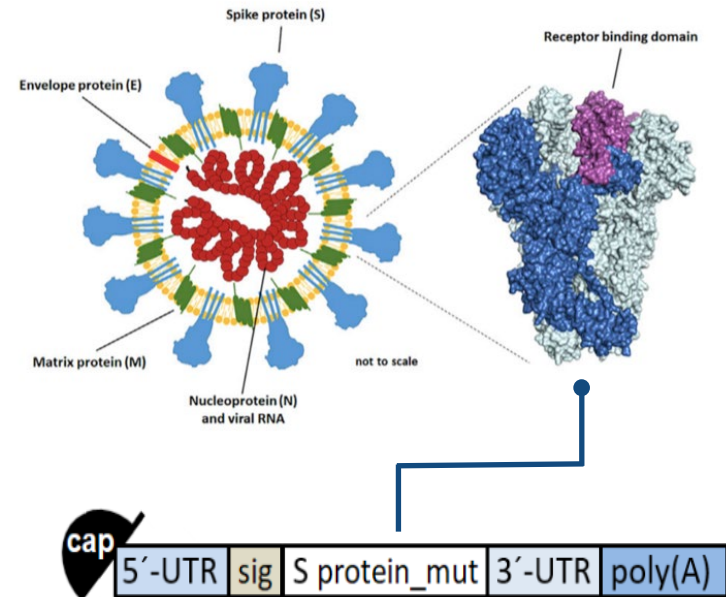
What is mRNA?

mRNA is biological software, cellular instructions to make any protein



mRNA as Vaccines

mRNA vaccines against SARS CoV 2 encode Spike protein.



Jeong DE et al, Virological.org 3-23-21

mRNA Vaccines against SARS CoV-2

Highly effective and safe



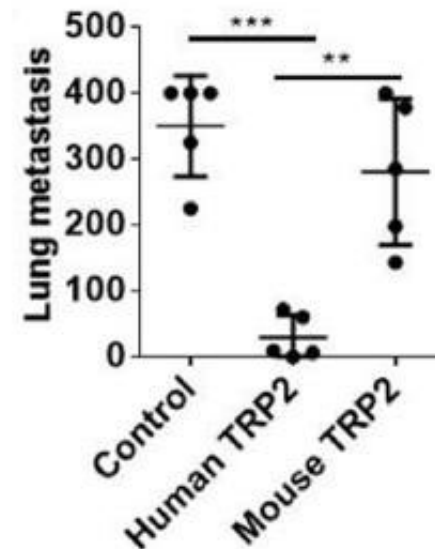
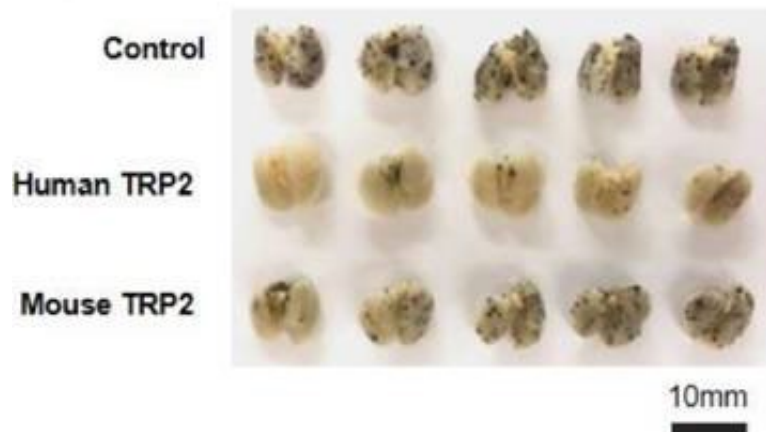
90%
Effective



94.5%
Effective

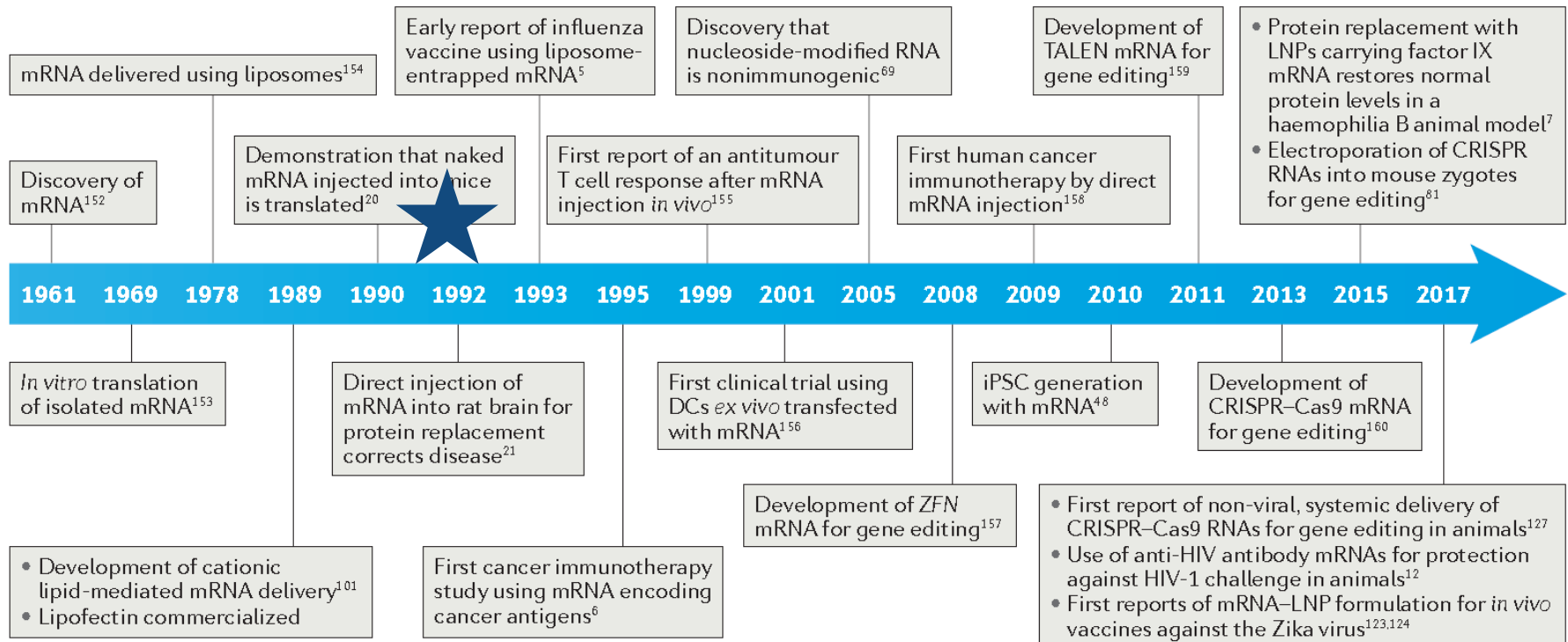


Melanoma Vaccine



Courtesy, Rong Fu Wang, HMH

Why mRNA? Why Now?



Hajj and Whitehead Nature Reviews Materials 2017

Why mRNA? Why Now?

Obstacles are being overcome

Systemic Delivery

Requires carrier that protects mRNA integrity and preferentially delivers to target cell

Intracellular Delivery

Requires carrier to cross cytoplasmic membrane

mRNA Toxicity

Innate immune activation

Short Half-life

RNAases are ubiquitous

Great Potential of mRNA Therapeutics

The Big 3: Market Cap (4.3.21)

 **\$17B**

 **\$27.5B**

 **\$53B**
messenger therapeutics

Rapid therapeutic development

- ✓ Writing code....like software
- ✓ New chemical entity to clinic.....15 years
RNA vaccine to clinic.....1y

Superior safety versus DNA drugs

- ✓ No integration into the host genome
- ✓ Simpler regulatory roadmap

Potential to replace a \$200B+ recombinant protein industry

- ✓ Simpler manufacturing process than recombinant proteins
- ✓ Endogenous post-translational modifications

Personalized RNA molecules

- ✓ Manufacturing process is rapid

mRNA Therapeutics: Moderna Pipeline and Partners

moderna®

- Founded in 2010
- Now ~30 products, mainly **cancer vaccines**
- 3 Major Pharma partners
- ~50B\$ valuation



Modality	Program #	Program Indication	Preclinical development	Phase 1	Phase 2	Phase 3	Commercial
Core modalities							
Prophylactic Vaccines	mRNA-1273	COVID-19 vaccine					
	mRNA-1647	Cytomegalovirus (CMV) vaccine					
	mRNA-1653	Human metapneumovirus and parainfluenza virus 3 (hMPV/PIV3) vaccine	Phase 1b (pediatrics)	Phase 1 (adults)			
	mRNA-1893	Zika vaccine					
	mRNA-1345	Respiratory syncytial virus (RSV) vaccine					
	mRNA-1010	Influenza vaccine					
	mRNA-1020						
	mRNA-1030						
	mRNA-1189	Epstein-Barr virus (EBV) vaccine					
	mRNA-1215	Nipah (NiV) vaccine					
Systemic Secreted & Cell Surface Therapeutics	mRNA-1644	HIV vaccine					
	mRNA-1574						
	mRNA-1851	Influenza H7N9 vaccine					
	mRNA-1944	Antibody against Chikungunya virus					
	AZD7970	Relaxin Heart failure					
Exploratory modalities	Cancer Vaccines	mRNA-4157	Personalized cancer vaccine (PCV)				
		mRNA-5671	KRAS vaccine				
	Intratumoral Immunology	mRNA-2416	OX40L Solid tumors/lymphoma Advanced ovarian carcinoma (Ph 2 cohort)	Solid tumors/lymphoma	Ovarian		
		mRNA-2752	OX40L/IL-23/IL-36γ (Triple) Solid tumors/lymphoma				
		MEDI1191	IL-12 Solid tumors				
	Localized Regenerative Therapeutics	AZD8601	VEGF-A Myocardial ischemia				
	Systemic Intracellular Therapeutics	mRNA-3927	PCCA/PCCB Propionic acidemia (PA)				
		mRNA-3705	MUT Methylmalonic acidemia (MMA)				
		mRNA-3283	PAH Phenylketonuria (PKU)				
		mRNA-3745	G6Pase Glycogen Storage Disorder Type 1a (GSD1a)				

CPRIT RNA Core

Growing business in Texas



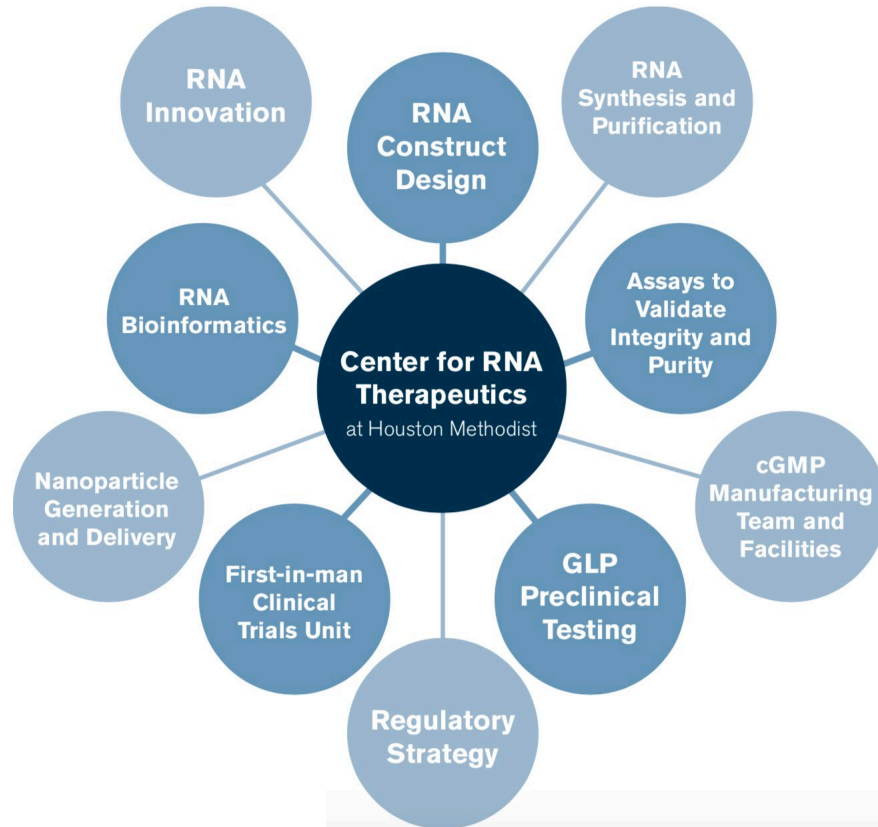
VGXI breaks ground on 44-acre site

Conroe TX, Deison Technology Park,
11-9-20

- **VGXI:** Large CMO for DNA vaccines
- Partnership generates a complete assembly line to support pre-clinical studies through commercialization
- HMH will generate RNA for Phase 1-2a Clinical Trials
- VGXI will generate large batches for Phase 2b-3 and commercialization

INSTITUTIONAL COMMITMENT OF HMH

FUNDING TO DEVELOP, MANUFACTURE, DELIVER AND TEST
NOVEL RNA THERAPIES



GLP, GMP, and First-in-Man facilities

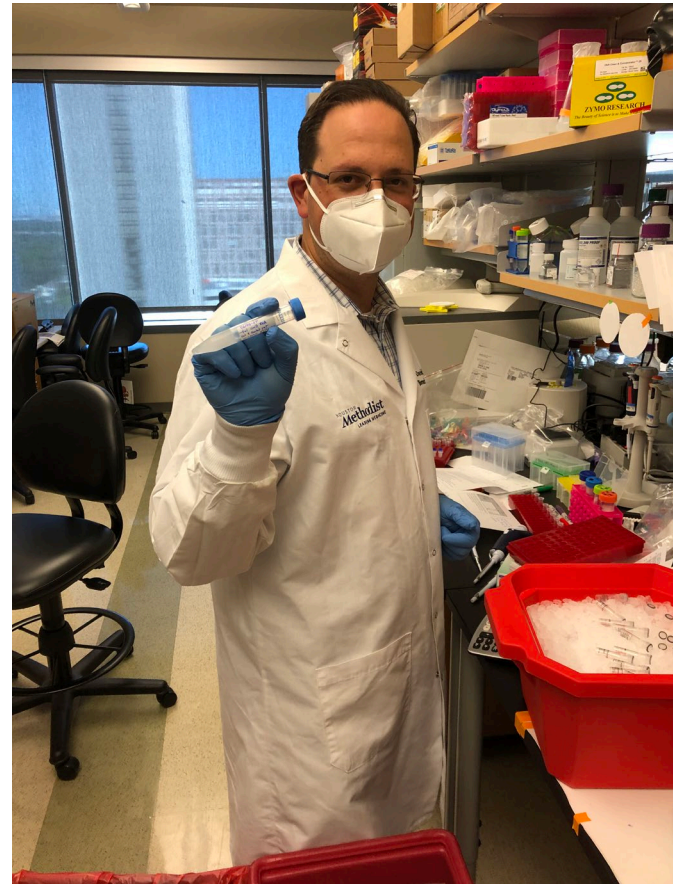
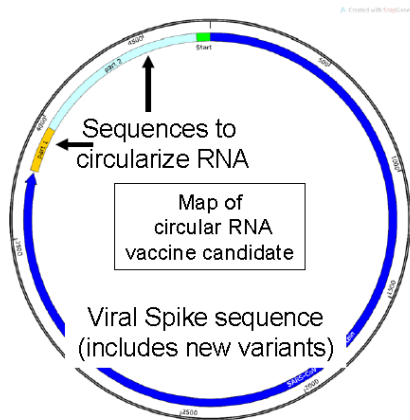
Center designation

1M\$/year commitment 2014-2027

Recruiting 4 more Faculty in RNA Biology/Chemistry

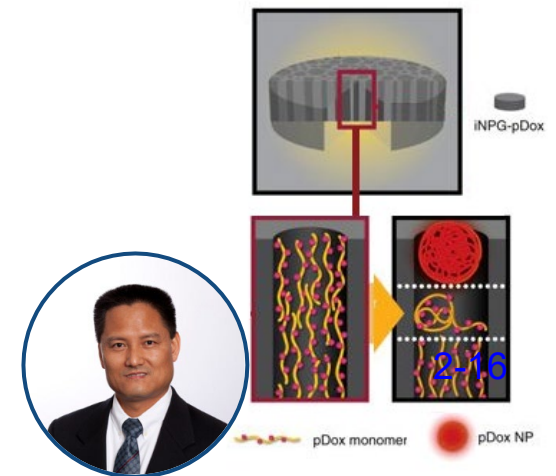
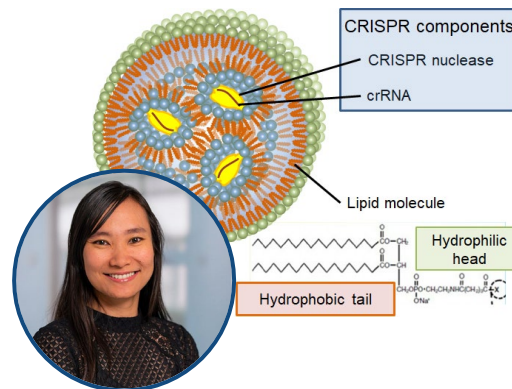
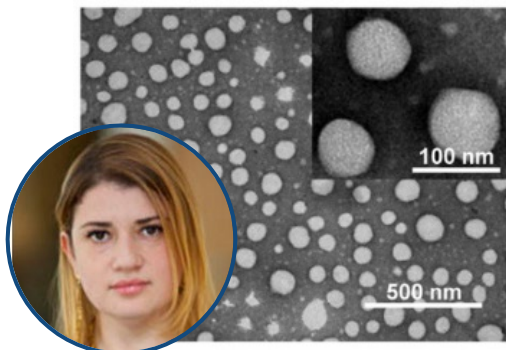
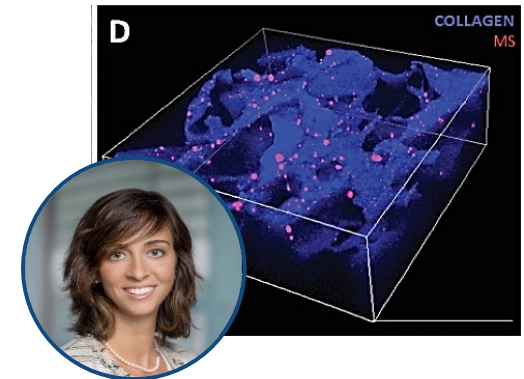
Circular mRNA

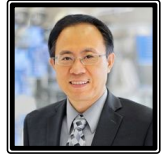
- mRNA degraded from ends
- Circular RNAs don't have ends and are harder to destroy
- Longer RNA lifespan = increased chance of effectiveness



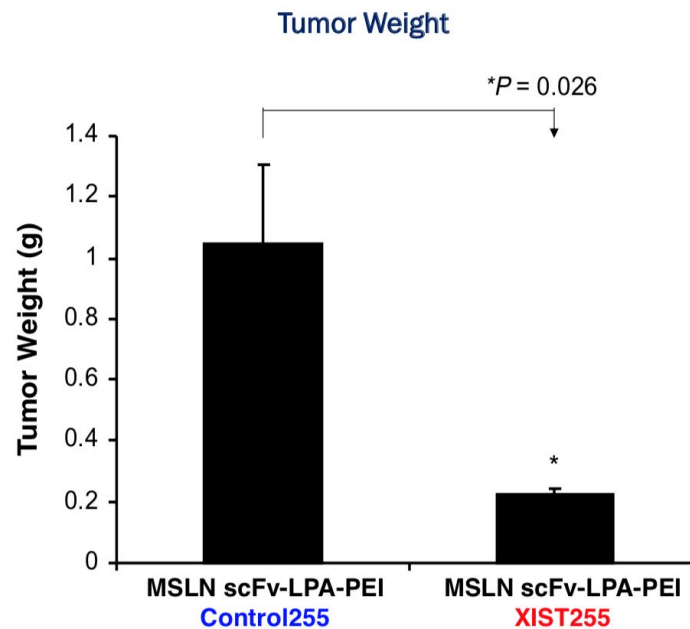
Delivery of mRNA uses lipid nanoparticles

The HMM Department of Nanomedicine: Develops Nanoparticles for RNA Delivery





RNA-based therapy for pancreatic cancer

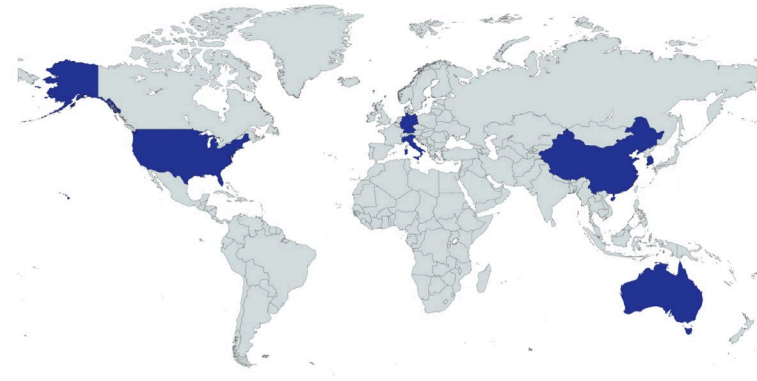


Courtesy, Dr. Changyi (Johnny) Chen, BCM

Supporting cancer investigators in Texas and beyond

Within past 5 years:

- Designed and developed over 100 unique RNA constructs
- Fulfilled over 300 orders from more than 40 different clients
- Manufactured ~ 10,900 ug RNA (~350 ug per order)
- Provided over 80 analytical services
- Published 26 manuscripts

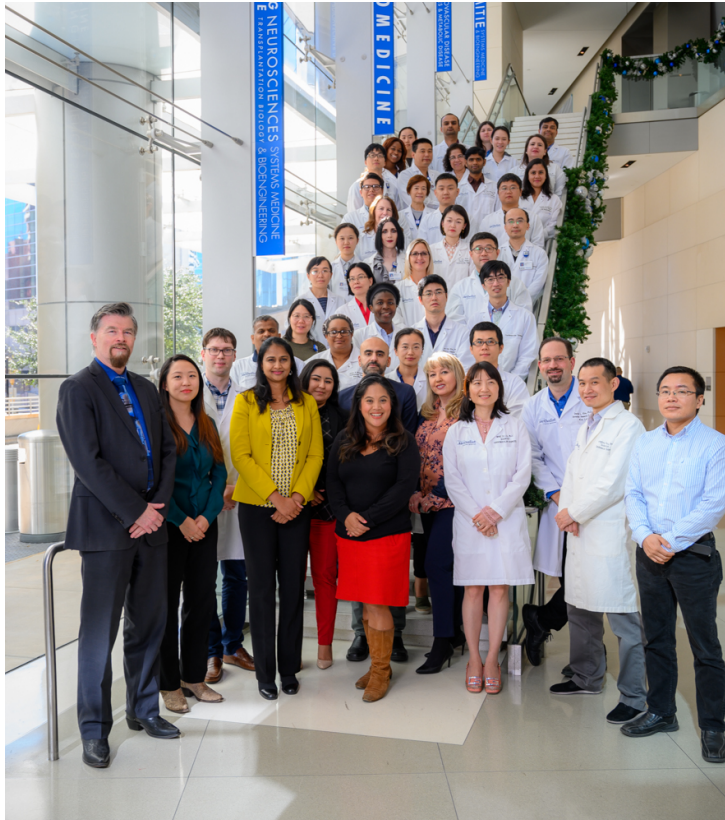


Supporting startups in Texas and beyond

Within past 5 years:

- Manufactured for 8 small biotech companies
- Supported clinical trials with analytical services for 3 biotech startups
- Consulted for 10 companies on RNA design, manufacturing, assessment, and delivery

RNA Therapeutics at HMH



NIH R01HL148016; R01HL132155;
R01HL149303; R01HL133254; Progeria
Research Foundation, **CPRIT RP150611**

Dan Kiss
Roman Sukhovshin
Nhat Tu Le
Longhou Fang
Ruli Gao
Francisco Altimarano
Biana Godin
Francesca Taraballi
Bruna Coradetti



Zhen Chen
Yingjun Luo



HARVARD
MEDICAL SCHOOL
Kaifu Chen



Louise McCullough



Rod Pettigrew
Abhishek Jain
Michael McShane



Nick Leeper
Ngan Huang



John Conner



Malcolm Brenner
Peter Hotez
Jeroen Pollet



Junichi Abe

2-20



CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

MEMORANDUM

TO: OVERSIGHT COMMITTEE MEMBERS
FROM: WAYNE ROBERTS, CHIEF EXECUTIVE OFFICER
SUBJECT: CHIEF EXECUTIVE OFFICER REPORT
DATE: MAY 10, 2021

I will address the items detailed below in my Chief Executive Officer Report presented at the May 19 Oversight Committee meeting. I have included copies of the March and April 2021 CPRIT Activity Updates behind this memo and attachments for your reference.

FY 2021 Grant Awards Funds Available and CPRIT Dashboard (Attachments 1 and 2)

CPRIT has \$242.4 million available from fiscal year 2021 appropriations for grant awards. There are sufficient funds to cover the Program Integration Committee's recommendations that Dr. Jim Willson and Ms. Ramona Magid will present at the May 19 meeting. I have also included CPRIT's dashboard of metrics the agency tracks on a regular basis.

CPRIT's Response to COVID-19 Related Issues

CPRIT staff continue to work remotely. I expect this to continue until mid-summer after we develop a new permanent partial work from home policy.

In-person Oversight Committee meetings should resume no later than the November 17, 2021, meeting. It is unlikely that the FY 2021 operating budget can accommodate Oversight Committee travel costs for an in-person August 18 Oversight Committee meeting. As previously reported, with the advent of videoconferenced meetings necessitated by the pandemic, we transferred the agency's FY 2021 travel budget to meet the unanticipated cost of the Chief Scientific Officer search firm contract.

Personnel

CPRIT currently has 34 of our 36 full-time equivalent (FTE) positions filled.

Chief Scientific Officer Search

On April 30 Spencer Stuart briefed Interview Committee Chair Dr. Bill Rice, Dr. Jim Willson, Lisa Nelson, and me on the initial list of applicants and/or nominations for CPRIT's Chief Scientific Officer position. We met again on May 14 with a third meeting planned for May 27 to review updated and refined lists. This preselection team will share its suggestions for the list of interview candidates with the full interview committee prior to a full committee review on or

around June 8. We plan two days of interviews for the week of June 28, with a possible second round interviews and recommendations of finalist(s) to me in the July-August timeframe.

Legislative Session Update

The 87th Texas Legislature will adjourn *Sine Die* at midnight May 31. The legislative pace has hit full stride and developments occur daily. The information reported below on CPRIT's budget, CPRIT-related legislation, other notable legislation is current as of 9:00 a.m., May 12. I will notify you regarding any notable legislative action.

General Appropriations Bills (Senate Bill 1 and House Bill 1)

Summary of CPRIT's Exceptional Items Budget Request

Exceptional Item Request	HB 1 filed	HAC subcomm	Full HAC	House	SB 1 filed	SFC subcomm	Full SFC	Senate
Base Adjustment for Ongoing Operating Costs	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes
8 New FTE Positions	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Budget Transfer Authority	Partial	Partial	Partial	Partial	Yes	Yes	Yes	Yes
CSO Exempt Salary Increase	No	Pend	Pend	Pend	No	Yes	Yes	Yes
SWCAP Base Adjustment	No	Yes	Yes	Yes	No	Yes	Yes	Yes

CPRIT is in an extremely favorable position regarding agency appropriations for fiscal years 2022-2023. Both chambers adopted versions of the general appropriations bill that provide full appropriations for CPRIT and include most (House Bill 1) or all (Senate Bill 1) of CPRIT's requested exceptional items, including eight new full time equivalent (FTE) positions and the SWCAP base adjustment. The only two exceptional item issues to resolve by the budget conference committee are the Chief Scientific Officer exempt salary increase and CPRIT's transfer authority. These recommendations are a definite sign of confidence in CPRIT and indicate the legislature's strong faith in the agency, our mission, and your leadership.

Background Regarding Budget Approval Process

The House and Senate released their general appropriations bills January 21. Both Senate Bill 1 (SB 1) and House Bill 1 (HB 1) as introduced provided CPRIT's full, constitutionally authorized annual appropriation of \$300 million less the required transfer of \$3.1 million per year to the Cancer Registry at the Texas Department of State Health Services. Unlike many state agencies, state leadership did not instruct CPRIT to make any reductions from its base request for 2022 and 2023. As reflected in the table above, SB 1 as introduced included several of CPRIT's requested changes. HB 1 as introduced took a more traditional approach, carrying forward CPRIT's previous appropriations with minimal adjustments.

The Senate Finance Committee (SFC) and the House Appropriations Committee (HAC) and their respective subcommittees held public hearings in February and March and worked with the budget analysts from the Legislative Budget Board (LBB) to review the budget recommendations for each agency. Ms. McConnell and I presented CPRIT's budget request to the Senate Committee on Finance on February 9 and to the House Committee on Appropriations Subcommittee on Articles I, IV and V on March 1.

On March 8, the Senate Finance Workgroup on Articles I, IV and V (Senators Huffman (chair), Campbell, Schwertner, Whitmire) released initial recommended changes to SB 1. The House Appropriations Subcommittee on Articles I, IV and V (Representatives M. González (chair), Ashby, Holland, Schaefer, Sherman) marked up CPRIT on March 17. Both subcommittees made recommendations to their full committees in CPRIT's favor. The full committees for the SFC and the HAC adopted their respective subcommittee's mark ups for CPRIT on March 24 (SFC) and March 30 (HAC).

The two chambers approved their version of the budget bills on April 6 (Senate) and April 22 (House). Each chamber designated members to negotiate the differences between the two bills. Senate conference committee members are: Senators Nelson (chair), Huffman, Kolkhorst, Nichols, and Taylor. The House conference committee members are Representatives Bonnen (chair), Capriglione, M. González, Walle, and Wilson. This budget conference committee will present the negotiated appropriations bill to each chamber for final approval in late May.

Budget Transfer Authority

Currently, the LBB (specifically the Chairs of HAC and SFC, the Lieutenant Governor, and the Speaker) must each individually approve a CPRIT transfer request before the agency may transfer appropriated funds between budget line items. These transfer requests are non-controversial but necessary to maintain operational stability. However, because of the multiple signoffs required for approval, CPRIT's budget transfer requests have languished administratively for months, with a recent request taking 115 days to get approved.

The Senate tracks our request by authorizing CPRIT's CEO, with Oversight Committee acknowledgement, to transfer up to 20 percent from one line item to another. Although CPRIT must report the transfer to the LBB, the Senate does not require additional approval before the transfer may occur. This is the standard budget transfer provision for most state agencies.

The House takes a different approach. It proposes limiting the window for rejecting CPRIT's budget transfer request to 30 days. Unless the HAC Chair, SFC Chair, the Lieutenant Governor or the Speaker specifically reject CPRIT's request, CPRIT may make the budget transfer on the 31st day. The House's proposed change is a significant improvement over CPRIT's current provision, but still treats CPRIT differently from most state agencies.

CPRIT-Related Legislation

- [Senate Bill 74/House Bill 4241](#) (companions)

Senator Borris Miles and Representative Jacey Jetton filed legislation amending CPRIT's statute (Tex. Health & Safety Code §102.255(d)) to allow research institutions or their affiliated centers to use the federal indirect rate as a credit to offset CPRIT's matching requirement. The credit is already available to institutions of higher education as defined by the Texas Education Code, but the amendment addresses the research institutions that do not qualify under Education Code designation.

Last action: HB 4241 referred to House Public Health Committee; the Senate Committee on Health & Human Services took testimony on SB 74 on April 28 and left the bill pending.

- [Senate Bill 713/House Bill 1860](#) (companions)
Representative John Cyrier and Senator Dawn Buckingham, in their respective roles as Chair and Vice Chair of the Sunset Commission, each introduced legislation to reorder several upcoming agency sunset reviews. The proposed legislation changes CPRIT's sunset review year from 2023 to 2029.

Last action: The Senate unanimously passed SB 713 on April 19 and the Speaker of the House referred the bill to the House State Affairs Committee. On April 29, the House State Affairs Committee reported SB 713 favorably out of committee. The bill is now in the House Calendars Committee for placement on an upcoming House calendar for consideration.

- [Senate Bill 1653/House Bill 3579](#) (companions)
Senators Juan "Chuy" Hinojosa and Eddie Lucio and Representative R.D. "Bobby" Guerra filed companion legislation that makes significant changes to CPRIT's enabling legislation.

One change would allow the Oversight Committee (OC) to consider and approve any application for grant awards, even those applications not recommended after peer review. If the OC does not vote to approve a grant application that a member pulls from the list of non-recommended applications for consideration, then the OC must record its reasoning for not approving the award(s) in the minutes of the meeting. Currently, the Program Integration Committee and the OC may only consider applications reviewed and recommended by the peer review panels for grant awards.

The second proposed change appears to alter the way that prevention grant funds would be allocated by requiring that CPRIT give the funding to specified counties rather than project leaders, even if there is no apparatus in the county to complete the project. The same section contains an unclear requirement that CPRIT fund projects in medically underserved areas with a health-related institution whose expenditure for research and development is not in the top three among health-related institutions and has a hospital; however, this money can only go to prevention "programming and operations."

The third proposed change would allow CPRIT to award any grant funds recovered from awards failing to meet the terms and conditions of their contracts to other projects in "the same grant cycle that CPRIT deems able to be "imminently commenced."

In addition to these three significant changes, the proposed legislation adds The University of Texas Rio Grande Valley School of Medicine to the list of universities from which the chancellor of The University of Texas System must choose two representatives to represent the system on CPRIT's University Advisory Committee.

Last action: Referred to Senate Health & Human Services, House Public Health Committees

- [House Bill 2252](#)
Representative Oliverson filed legislation that would prohibit CPRIT from awarding a grant to an applicant that plans to buy organs from a hospital in China. The bill also requires CPRIT to add a written contract certification that the grantee will not use grant funds to buy organs from a hospital in China for all awards, including those made prior to the effective date of the bill. On March 15 I discussed Mr. Oliverson's concerns with his staff. Based on this discussion we provided alternative language that should address the representative's concerns in a way that minimizes administrative burdens on CPRIT.

Last action: Referred to House Public Health

Other Notable Legislation

- [House Joint Resolution 5](#) and [House Bill 15](#)
Representative Senfronia Thompson filed legislation to create the Brain Institute of Texas. The House Higher Education Committee adopted committee substitutes for HJR 5 and HB 15. The House approved HJR 5 on April 27 by a vote of 114 Yeas, 33 Nays, and 1 Present Not Voting; the House approved HB 15 on April 28 by a vote of 107 Yeas, 36 Nays, and 1 Present Not Voting. The Senate received both pieces of legislation on April 28. Lt. Governor Patrick referred both bills to the Senate Health & Human Services Committee on May 10. The committee has not scheduled a hearing.
- [Senate Joint Resolution 17](#) and [Senate Bill 264](#)
Senator Jose Menéndez filed legislation to create the Texas Research Consortium to Cure Infectious Diseases (TRANSCEND) with a \$3 billion constitutional bond authorization. Senator Menéndez explained that he intends CPRIT to serve as a model for the new agency. The Lt. Governor referred the proposed legislation to the Senate Health & Human Services Committee. The committee has not scheduled a hearing on the proposed legislation.

2022 Innovations Conference

Staff began discussions on resuming CPRIT's *Innovations* Conference in 2022. You will recall that CPRIT cancelled the July 2020 conference due to the pandemic. Initial timing appears to be summer/fall 2022, subject to hotel and venue interest. Planning will begin in late summer.

233 Stellar Recruits Brought to Texas Since 2007

As of May 3, CPRIT has successfully recruited 233 eminent scholars at all career stages to Texas institutions of higher education. Using a modeling method developed by Oversight Committee

member Dr. Bill Rice, these recruits represent over 6,200 future research years brought to Texas by the recruitment mechanism in Academic Research since 2007.

We are on track to reach 250 recruited scholars to Texas by the August Oversight Committee meeting. This metric is a great accolade to Dr. Willson and CPRIT. When Dr. Willson started at CPRIT the milestone was 100 recruitments. We have also seen a steady increase in the number of female scholars in CPRIT's portfolio over the past five years, with The University of Texas MD Anderson Cancer Center leading the way.

CPRIT has awarded **1,585** grants totaling **\$2.669 billion**

- 244 prevention awards totaling \$277.7 million
- 1,341 academic research and product development research awards totaling \$2.392 billion

Of the \$2.392 billion in academic research and product development research awards,

- 30.5% of the funding (\$730.0 million) supports clinical research projects
- 24.4% of the funding (\$582.0 million) supports translational research projects
- 28.9% of funding (\$691.6 million) supports recruitment awards
- 13.7% of the funding (\$327.7 million) supports discovery stage research projects
- 2.5% of funding (\$60.0 million) supports training programs.

CPRIT has 12 open Requests for Applications (RFAs)

- 3 Research Recruitment
- 5 Academic Research
- 4 Prevention

FY 2021 GRANT AWARD FUNDS AVAILABLE

General Obligation Bond Proceeds

	Prevention	Academic / Product Development Research	1% Grant Funding Buffer	Operating Budget	Total Appropriations
Available Appropriated Funds	\$ 28,035,081	\$ 254,738,136		\$ 17,226,783	\$ 300,000,000
Pending Adjustment to Operating Budget		\$ (448,525)		\$ 448,525	
Approved Adjustment to Operating Budget		\$ (2,484,576)		\$ 2,484,576	
Appropriations Transfer to DSHS		\$ (3,118,032)		\$ 3,118,032	
Adjusted Appropriations	\$ 28,035,081	\$ 248,687,003		\$ 23,277,916	\$ 300,000,000
Total Available for All Grants			\$ 276,722,084		
1% of Total Available Grant Funding			\$ 2,767,221		
Adjusted Grant Award Funding	28,035,081	245,919,782			\$ 273,954,863
	Prevention Grants	Academic Research Grants	PD Research Grants		
Total Available for Grant Awards (Total GO Bond Proceeds Less Operating Budget)	\$ 28,035,081	\$ 174,080,902	\$ 74,606,101		\$ 276,722,084
Total Available for Grant Awards Incorporating 1% Grant Funding Buffer	\$ 28,035,081	\$ 172,454,675	\$ 73,909,147		\$ 274,398,903
Announced Grant Awards					
11/18/20 Recruitment Awards	\$ -	\$ 26,000,000	\$ -		
2/17/21 Recruitment Awards (2)		\$ 12,000,000			
	\$ -	\$ -	\$ -		
	\$ -	\$ -			
Announced Grant Award Subtotal	\$ -	\$ 38,000,000	\$ -	\$ -	\$ 38,000,000
Grant Award Adjustments					
4/16/21 Declined Recruit (BCM-Iliopoulos)	\$ -	\$ (6,000,000.00)	\$ -		\$ (6,000,000)
	\$ -	\$ -	\$ -		\$ -
	\$ -	\$ -	\$ -		\$ -
	\$ -	\$ -	\$ -		\$ -
Revised Grant Award Subtotal	\$ -	\$ 32,000,000	\$ -		\$ 32,000,000
Uncommitted Funds as of April 28, 2021	\$ 28,035,081	\$ 140,454,675	\$ 73,909,147		\$ 242,398,903
Pending Grant Awards-PIC Recommendations					
Prevention Awards (5)	\$ 11,202,949	\$ -	\$ -		
Recruitment Awards (13)	\$ -	\$ 30,000,000	\$ -		
Research Training Awards (8)	\$ -	\$ 30,320,920	\$ -		
Pending Grant Award Subtotal	\$ 11,202,949	\$ 60,320,920	\$ -		\$ 71,523,869
Total Pending Grant & Grant Funds Committed	\$ 11,202,949	\$ 92,320,920	\$ -		\$ 103,523,869
Uncommitted Funds as of May 12, 2021	\$ 16,832,132	\$ 80,133,755	\$ 73,909,147		\$ 170,875,034
1% Grant Funding Buffer	\$ -	\$ 1,626,227	\$ 696,954		\$ 2,323,181
Total Remaining Funds	\$ 16,832,132	\$ 81,759,982	\$ 74,606,101		\$ 173,198,215
Operating Budget Detail					
Indirect Administration				\$ 4,828,578	
Grant Review & Award Operations				\$ 15,331,306	
Subtotal, CPRIT Operating Costs				\$ 20,159,884	
Cancer Registry Operating Cost Transfer				\$ 3,118,032	
Total, Operating Costs				\$ 23,277,916	

**CPRIT MANAGEMENT DASHBOARD
FISCAL YEAR 2021**

	SEPT	OCT	NOV	DEC	JAN	FEB	MAR	APR	MAY	JUN	JUL	AUG	CUMULATIVE (ANNUAL)	CUMULATIVE (TO DATE)
ACCOUNTABILITY														
Announced Grant Awards			62			2							64	
New Grant Contracts Signed	13	33	6	5	10	4	2	6					79	
New Grant Contracts In Negotiation			12			5							17	
Grant Reimbursements Processed (#)	208	195	209	142	128	119	242	171					1414	
Grant Reimbursements Processed (\$)	\$ 24,277,590	\$ 21,609,925	\$ 11,437,454	\$ 25,234,475	\$ 14,976,404	\$ 13,896,416	\$ 21,383,991	\$ 27,269,422					\$ 160,085,678	
Revenue Sharing Payments Received	\$ -	\$ -	\$ 44,809	\$ -	\$ -	\$ 22,845	\$ 100,000	\$ 4,550					\$ 172,205	\$ 4,836,704
Grants Awarded (#)/ Applications Rec'd (#)	18%	18%	19%	18%	18%	18%	18%	18%						
Grantee Compliance Trainings	0	4	2	1	0	0	4	1					12	
Grantee Compliance Monitoring Visits	0	0	2	2	3	2	2	6					17	
Awards with Delinquent Reimbursement Submission (FSR)			14			2								
Awards with Delinquent Matching Funds Verification			0			3								
Awards with Delinquent Progress Report Submission			4			1								
MISSION														
Open RFAs	11	13	13	13	16	7	8	8						
Prevention Applications Received	0	12	0	0	0	22	0	0					34	903
Product Development Applications Received	0	0	0	0	36	0	0	0					36	597
Academic Research Applications Received	0	17	2	4	162	6	11	9					211	7,756
Help Desk Calls/Emails	85	123	72	94	225	124	139	137					999	
Number of Research Grants Announced (Annual)	0		52			2							54	
Recruited Scientists Contracted														228
Number of Product Development Grants Announced (Annual)			2			0							2	
Life Science Companies Recruited (in TX)														11
Number of Product Development Jobs Created & Maintained														738
Number of Prevention Grants Announced (Annual)			8			0							8	
Total Number of Education, Navigation and Training Services			177,077			132,058							309,135	
Total Number of Clinical Services			57,327			40,111							97,438	
Published Articles on CPRIT-Funded Projects (#)														
Clinical Studies (#)														160
Number of Patent Applications														
Number of Patents Resulting from Research														
TRANSPARENCY														
Total Website Hits (Sessions)	8,582	8,651	10,366	6,975	9,422	6,775	9,172	8,372						
Total Unique Visitors to Website (Users)	6,409	6,646	8,474	5,351	6,762	5,601	7,130	6,326						



CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

MEMORANDUM

TO: OVERSIGHT COMMITTEE MEMBERS
FROM: WAYNE R. ROBERTS, CHIEF EXECUTIVE OFFICER
SUBJECT: CPRIT ACTIVITIES UPDATE FOR MARCH
DATE: MARCH 31, 2021

Topics in this memo include CPRIT activities in February and March, recent milestones in the fight against cancer, a staffing summary, a legislative update, outreach efforts, and news from Compliance, Programs, and Operations.

Recent Milestones in the Fight Against Cancer

CPRIT Grantees in the News

- CPRIT Scholar Dr. Hao Zhu, an associate professor at The University of Texas Southwestern Medical Center, received the 2021 Mark Foundation Emerging Leader Award on February 1 to support his research to identify therapeutic approaches to increase the effectiveness of immune checkpoint inhibitors across different types of cancer. UT Southwestern recruited Dr. Zhu with the support of a CPRIT Recruitment of First-Time, Tenure-Track Faculty grant in 2012 (R1209). Dr. Zhu has received three additional CPRIT research awards addressing liver cancer (DP150077, RP170267, and RP180268).
- The Alfred P. Sloan Foundation announced February 17 that CPRIT Scholar Urbain Weyemi, Ph.D., an assistant professor at The University of Texas at Austin is among the 128 scholars from across the country to receive 2021 Sloan Research Fellowships. These fellowships honor outstanding early-career scientists in eight fields. Dr. Weyemi joined the Department of Molecular Biosciences as a CPRIT Scholar in 2019 (RR190101). He researches at the intersection of cancer biology, neurodegeneration, and epigenetics, focusing on how damage to human DNA leads to cancer and other diseases.
- Iterion Therapeutics, Inc. announced February 22 that the company raised \$17 million in a funding round to support the development of its lead drug candidate, Tegavivint, for a Phase 1/2a clinical trial in patients with desmoid tumors. Houston-based Iterion received a \$15.9 million CPRIT Product Development Research award (CP130058) in 2014 to fund the development of Tegavivint for desmoid tumors and acute myeloid leukemia.
- The Welch Foundation announced February 23 that it selected CPRIT Scholar Ilya Finkelstein, Ph.D., to receive the 2021 Norman Hackerman Award in Chemical Research.

Having made significant scientific contributions to understand how cells repair their DNA and maintain integrity of genetic information, the Norman Hackerman award recognizes Dr. Finkelstein as a rising star in his field. Most recently, Dr. Finkelstein, an associate professor of molecular biosciences at The University of Texas at Austin, shifted his team's focus and developed a critical reagent for SARS-CoV-2 vaccine development. His group, in collaboration with the UT Austin labs of fellow molecular bioscientist Jason McLellan, designed a new version of the critical coronavirus spike protein that, when expressed in cells, produces significantly more protein and is more stable for use in vaccines. UT Austin recruited Dr. Finkelstein with a CPRIT Recruitment of First-Time, Tenure-Track Faculty grant in 2021 (R1214). CPRIT also awarded Dr. Finkelstein a \$900,000 grant in 2019 (RP190301) to study biophysical mechanisms of human microhomology-mediated end joining.

- Houston-based Salaria Pharmaceuticals, Inc. announced February 24 the expansion stage of a Phase 1/2 clinical trial of their lead drug candidate, Seclidemstat, in patients with Ewing sarcoma and Ewing-related sarcomas. Salaria received an \$18.7 million CPRIT Product Development Research Award (DP160014) in 2016 to support their Ewing sarcoma clinical trial.
- Aeglea Biotherapeutics, Inc. appointed life sciences investor Sara Brownstein to the company's board of directors on February 24. Ms. Brownstein serves as a principal at Baker Bros. Advisors LP. Austin-based Aeglea received a \$19.8 million CPRIT Product Development Research award (DP140031) in 2014 to support the development of an engineered human arginase targeting multiple cancer types.
- On February 25, the "Break Through Cancer" alliance announced its formal launch as a public foundation designed to find new solutions to intractable cancers. The University of Texas MD Anderson Cancer Center and four other leading cancer research centers - Dana-Farber Cancer Institute, the Sidney Kimmel Comprehensive Cancer Center at Johns Hopkins, Memorial Sloan Kettering Cancer Center, and the Koch Institute for Integrative Cancer Research at MIT - form this unique research alliance. Mr. and Mrs. William Hunter Goodwin, Jr. and their family funded the alliance with a pledge of \$250 million to focus on four cancer types—pancreatic cancer, ovarian cancer, glioblastoma, and acute myelogenous leukemia. The alliance will promote collaborations among these leading cancer research centers to bring new approaches and new thinking to accelerate research, clinical trials, and, ultimately, cures for the deadliest cancers.
- Perimeter Medical Imaging AI, Inc received U.S. Food and Drug Administration 510(k) clearance for their OCT imaging system on March 1. Perimeter created the OCT Imaging System for use as an imaging tool in the evaluation of excised human tissue microstructure by providing two-dimensional, cross-sectional, real-time depth visualization with image review manipulation software for identifying and annotating regions of interest. Perimeter, based in Toronto and Dallas, received a \$7.4 million CPRIT Product Development Research award (DP190087) in 2019 to fund the development of an optical tissue imaging system for breast conserving surgery.

- Austin-based Asuragen, Inc. announced March 3 that global life sciences company Bio-Techne Corporation (NASDAQ: TECH) will pay \$215 million in cash to acquire Asuragen. In addition to the upfront payment, Bio-Techne will pay additional consideration of up to \$105 million contingent upon the achievement of certain future milestones.

Asuragen is a molecular diagnostics company with a portfolio of diagnostic testing kits currently on market. Asuragen received a \$6.8 million CPRIT Product Development Research award (CP120017) in 2012 to support the development of next generation sequencing assays to enable detection of clinically relevant cancer-related gene mutations.

- Dialectic Therapeutics, Inc. announced March 3 that the company has received FDA clearance of their IND application for lead candidate DT2216, an anticancer agent targeting BCL-XL, the most commonly over-expressed antiapoptotic protein in cancer. Dallas-based Dialectic received a \$3 million CPRIT Product Development Research award (DP200018) in 2020 to support the development of DT2216.
- On March 8, Aravive, Inc. announced that clinicians had dosed the first patient in a Phase 1b/2 clinical trial of AVB-500 in patients with clear cell renal cell carcinoma. Aravive, based in Houston and Palo Alto, received a \$20 million CPRIT Product Development Research award (DP150127) in 2015 to support the development of AVB-500, an engineered AXL decoy receptor for the treatment of ovarian cancer.
- On March 17 Immatics N.V. presented a data update from the company's dose escalation cohorts in its ongoing ACTengine cell therapy programs. The ACTengine product candidates IMA201, IMA202 and IMA203 harness the patient's own T cells, which researchers have genetically engineered to express a novel, proprietary T cell receptor directed against a defined cancer target. Treatment with ACTengine product candidates at initial dose levels indicated early anti-tumor activity, with nine out of ten patients showing disease control, and tumor shrinkage observed in eight out of ten patients, including one partial response. The clinical observations were consistent with robust engraftment, persistence and tumor infiltration of infused ACTengine T cells.

Houston-based Immatics US, Inc. received a \$19.7 million CPRIT Product Development Research award (DP150029) in 2015 for the development of personalized cellular therapies targeting multiple cancer types. The clinical-stage biopharmaceutical company is active in the discovery and development of T cell-redirecting cancer immunotherapies.

Notable CPRIT-Supported Research Accomplishments

- A study led by Dr. Bert O'Malley, chancellor and professor of molecular and cellular biology at Baylor College of Medicine, uncovered a novel role of the steroid receptor coactivator 3 (SRC-3/NCOA3). This is a protein crucial for steroid hormone function and a prognostic marker for aggressive human breast and other cancers. Dr. O'Malley's team discovered that SRC-3/NCOA3 regulates human immune T regulatory cells (Tregs), which contribute to the

regulation of the body's immunological activity by suppressing the function of other immune cells, including those involved in fighting cancer. The study, which appears in the February 9, 2021, edition of the journal *Scientific Reports*, shows that Tregs without the SRC-3 function failed to suppress the activity of other immune cells in the lab. The studies, supported in part by CPRIT grants (RP100348, RP101251 and RP170500), may help in the fight against cancer in the future by leading to new approaches to inhibit Tregs activity which consequently would release immune attack in tumors.

- CPRIT Scholar Isaac Hilton, Ph.D., assistant professor of bioengineering and biosciences, at Rice University reported in the February 9, 2021, edition of the journal *Nature Communications* on a new tool to engineer and understand how human genes activate. His group created a synthetic protein to deliver chemical payloads at precise spots near human genes. The researchers then used this tool to identify genes linked to melanoma resistance. Tools like this can pave the way towards understanding how normal cellular processes go awry in human diseases. Rice recruited Dr. Hilton in 2017 with the support of a CPRIT Recruitment of First-Time, Tenure-Track Faculty grant (RR170030).
- CPRIT Scholar Sean Morrison, director of the Children's Medical Center Research Institute at The University of Texas Southwestern Medical Center, reported in the February 24, 2021, edition of the journal *Nature* on how mechanical forces can influence cellular growth and differentiation in bone marrow, providing a possible new explanation for how exercise strengthens bones and the immune system. It is well known that aging weakens bones and running can help strengthen them. Scientists thought that the mechanical forces from running act on the bone itself, but that the bones insulated the soft bone marrow inside bones from those mechanical forces. Dr. Morrison's work counters the insulation theory and shows that arteriolar blood vessels that go through the bone surface to the marrow transmit movement-induced mechanical forces and thereby stimulate the proliferation of bone- and immune-cell precursors by a growth factor, which the Morrison lab named ostelectin, that helps maintain bone mass in adult mice by stimulating the formation of bone cells in the marrow. UT Southwestern recruited Dr. Morrison to Texas in 2011 with a CPRIT Recruitment of Established Investigators award. CPRIT has also awarded Dr. Morrison three additional grants (RP170114, RP170633, and RP180778) totaling more than \$7 million for the study of melanoma.

Personnel

CPRIT has filled 34 of our 36 full-time equivalent (FTE) positions.

Chief Scientific Officer Search

After finalizing the search firm contract with Spencer Stuart March 9, CPRIT Operations Manager Lisa Nelson and I video-conferenced with Spencer Stuart to discuss broad parameters of the search. We also talked with Dr. Rice, who is chairing the interview committee, about general search process details. The first meeting of the full interview committee took place

March 29 via videoconference to discuss the process and our expectations. CPRIT will release the job description posting on April 2. Following a prequalification process, candidate interviews will take place in June and July. I will update the Oversight Committee as developments warrant.

CPRIT Outreach

Staff outreach activities during February and March include:

- Senior Program Manager for Product Development Rosemary French attended the webinar *Medical Device Packaging & Validation - More To It Than You Think* hosted by the Texas Medical Device Alliance on February 25.
- Chief Product Development Officer Dr. Cindy WalkerPeach and Ms. French attended the event *Collaborating with Johnson and Johnson: Academic Research Opportunities* hosted by Johnson and Johnson Innovation on February 26.
- Chief Scientific Officer Dr. Jim Willson moderated a session on March 9 for the Texas Science Festival: Science Sparks series hosted by The University of Texas at Austin College of Natural Sciences. More than 780 students attended the virtual session “*Big Strides in Fighting Cancer.*” CPRIT Scholar and Nobel Prize winner Dr. James Allison and CPRIT grantee Dr. Livia Eberlin were the featured panelists. Dr. Eberlin is the CPRIT-supported inventor of the MasSpec Pen, a device that can detect cancer during surgery in real-time.
- Dr. WalkerPeach attended the Texas Healthcare and Bioscience Institute Virtual Spring Policy Summit held March 10.
- Several staff members met with cancer advocates via videoconference on March 17 to discuss pending legislation that affects CPRIT.

Legislative Session Update

The 87th Texas Legislature convened at noon on January 12 and adjourns *Sine Die* at midnight May 31. All information I report below on CPRIT’s budget, CPRIT-related legislation, other notable legislation, and CPRIT’s legislation outreach and testimony is current as of noon, March 31. We are entering the time during the legislative session when action moves quickly. I will notify you regarding any notable legislative action.

General Appropriations Bills (Senate Bill 1 and House Bill 1)

CPRIT is in an extremely favorable position regarding agency appropriations for fiscal years 2022-2023. The Senate Finance Committee (SFC) and the House Appropriations Committee

(HAC) have each passed versions of the general appropriation bills that provide full appropriations for CPRIT and include most (House Bill 1) or all (Senate Bill 1) of CPRIT's requested exceptional items, including eight new full time equivalent (FTE) positions and the SWCAP base adjustment.

If each chamber adopts the bills for CPRIT as proposed, the only exceptional item issues to resolve in budget conference committee are the Chief Scientific Officer exempt salary increase and CPRIT's transfer authority. This is a definite sign of confidence in CPRIT and indicates the legislature's strong faith in the agency, our mission, and your leadership.

Background Regarding Budget Approval Process

The House and Senate released their general appropriations bills January 21. Both Senate Bill 1 (SB 1) and House Bill 1 (HB 1) as introduced provided CPRIT's full, constitutionally authorized annual appropriation of \$300 million less the required transfer of \$3.1 million per year to the Cancer Registry at the Texas Department of State Health Services. Unlike many state agencies, state leadership did not instruct CPRIT to make any reductions from its base request for 2022 and 2023. As reflected in the table below, SB 1 as introduced included several of CPRIT's requested changes. HB 1 as introduced took a more traditional approach, carrying forward CPRIT's previous appropriations with minimal adjustments.

The Senate Finance Committee (SFC) and the House Appropriations Committee (HAC) and their respective subcommittees held public hearings in February and March and worked with the budget analysts from the Legislative Budget Board (LBB) to review the budget recommendations for each agency. Ms. McConnell and I presented CPRIT's budget request to the Senate Committee on Finance on February 9 and to the House Committee on Appropriations Subcommittee on Articles I, IV and V on March 1.

On March 8, the Senate Finance Workgroup on Articles I, IV and V (Senators Huffman (c), Campbell, Schwertner, Whitmire) released initial recommended changes to SB 1. The House Appropriations Subcommittee on Articles I, IV and V (Representatives Mary González (c), Ashby, Holland, Schaefer, Sherman) marked up CPRIT on March 17. Both subcommittees made recommendations to their full committees in CPRIT's favor. The full committees for the SFC and the HAC adopted their respective subcommittee's mark ups for CPRIT on March 24 (SFC) and March 30 (HAC).

The revised appropriations bills now move to their respective chambers for consideration and approval. I expect Senator Nelson to lay out SB 1 on April 6. The House will likely take up HB 1 soon after. Once the Senate and House approve their versions of the general appropriations bill, each chamber will designate several members to negotiate the differences between SB 1 and HB 1. This conference committee will present the negotiated appropriations bill to each chamber for final approval, likely in late May.

Exceptional Item Request	HB 1 filed	HAC subcomm	Full HAC	SB 1 filed	SFC subcomm	Full SFC
Base Adjustment for Ongoing Operating Costs	No	Yes	Yes	Yes	Yes	Yes
8 New FTE Positions	No	Yes	Yes	Yes	Yes	Yes
Transfer Authority (see explanation)	Partial	Partial	Partial	Yes	Yes	Yes
CSO Exempt Salary Increase	No	Pend	Pend	No	Yes	Yes
SWCAP Base Adjustment	No	Yes	Yes	No	Yes	Yes

- *Budget Transfer Authority Explanation*

Currently, the LBB (specifically the Chairs of HAC and SFC, the Lieutenant Governor, and the Speaker) must each individually approve a CPRIT transfer request before the agency may transfer appropriated funds between budget line items. These transfer requests are non-controversial but necessary to maintain operational stability. However, because of the multiple signoffs required for approval, CPRIT's budget transfer requests have languished administratively for months, with our most recent request taking 115 days to get approved.

SB 1, which tracks our request, authorizes CPRIT's CEO, with Oversight Committee acknowledgement, to transfer up to 20 percent from one line item to another. Although CPRIT must report the transfer to the LBB, Senate Bill 1 does not require additional approval before the transfer may occur. This is the standard budget transfer provision for most state agencies.

HB 1 takes a different approach. It proposes limiting the window for rejecting CPRIT's budget transfer request to 30 days. Unless the HAC Chair, SFC Chair, the Lieutenant Governor or the Speaker specifically reject CPRIT's request, CPRIT may make the budget transfer on the 31st day. The House's proposed change is a significant improvement over CPRIT's current provision, but still treats CPRIT differently from most state agencies.

CPRIT-Related Legislation

- [Senate Bill 74/House Bill 4241](#) (companions)
Senator Boris Miles and Representative Jacey Jetton filed legislation amending CPRIT's statute (Tex. Health & Safety Code §102.255(d)) to allow research institutions or their affiliated centers to use the federal indirect rate as a credit to offset CPRIT's matching requirement. The credit is already available to institutions of higher education as defined by the Texas Education Code, but the amendment addresses the research institutions that do not qualify under Education Code designation.

Last action: Referred to Senate Health & Human Services, House Public Health Committees

- [Senate Bill 1563/House Bill 3579](#) (companions)
Senators Juan Hinojosa and Eddie Lucio and Representative Bobby Guerra filed companion legislation that makes three significant changes to CPRIT's enabling legislation.

One proposed change would allow the Oversight Committee to consider and approve any application for grant awards, even those applications not recommended after peer review. If the Oversight Committee does not vote to approve a grant application that a member pulls from the list of non-recommended applications for consideration, then the Oversight Committee must record its reasoning for not approving the award(s) in the minutes of the meeting. Currently, the Program Integration Committee and the Oversight Committee may only consider applications reviewed and recommended by the peer review panels for grant awards. Note: I have attached a one-pager that CPRIT uses to explain the importance of peer review to the integrity of our awards. Also attached is a document explaining CPRIT's proposed initiatives to increase regional research opportunities.

The second proposed change appears to alter the way that prevention grant funds would be allocated by requiring that CPRIT give the funding to specified counties rather than project leaders, even if there is no apparatus in the county to complete the project. The same section contains an unclear requirement that CPRIT fund projects in medically underserved areas with a health-related institution whose expenditure for research and development is not in the top three among health-related institutions and has a hospital (however this money can only go to prevention "programming and operations").

The third proposed change would allow CPRIT to award any grant funds recovered from awards failing to meet the terms and conditions of their contracts to other projects in "the same grant cycle" that CPRIT deems able to be "imminently commenced."

In addition to these three significant changes, the proposed legislation adds The University of Texas Rio Grande Valley School of Medicine to the list of universities from which the chancellor of The University of Texas System must choose two representatives to represent the system on CPRIT's University Advisory Committee.

Last action: Referred to Senate Health & Human Services, House Public Health Committees

- [House Bill 2252](#)
Representative Oliverson filed legislation that would prohibit CPRIT from awarding a grant to an applicant that plans to buy organs from a hospital in China. The bill also requires CPRIT to add a written contract certification that the grantee will not use grant funds to buy organs from a hospital in China for all awards, including those made prior to the effective date of the bill. On March 15 I discussed Mr. Oliverson's concerns with his staff. Based on this discussion we provided alternative language that should address the representative's concerns in a way that minimizes administrative burdens on CPRIT.

Last action: Referred to House Public Health

Other Notable Legislation

- [House Joint Resolution 5](#) and [House Bill 15](#)
Representative Senfronia Thompson filed legislation to create the Brain Institute of Texas. The House Higher Education Committee has scheduled the proposed legislation for hearing April 1.
- [Senate Joint Resolution 17](#) and [Senate Bill 264](#)
Senator Jose Menéndez filed legislation to create the Texas Research Consortium to Cure Infectious Diseases (TRANSCEND) with a \$3 billion constitutional bond authorization. Senator Menéndez explained that he intends CPRIT to serve as a model for the new agency. The Lt. Governor referred the proposed legislation to the Senate Health & Human Services Committee. The committee has not scheduled a hearing on the proposed legislation.

Non-Budget Related Testimony and Legislative Outreach

I testified about CPRIT and our activities at the March 3 House Committee on Public Health at the request of Chair Stephanie Klick.

In February and March, CPRIT met with the following legislators and/or their staff regarding our budget requests and other CPRIT legislation.

- February 23 - staff of Representative Carl Sherman, Sr.
- February 25 - Representative Trent Ashby
- February 25 - Representative Mary González
- February 25 - staff of Representative Justin Holland
- March 2 – Representative Stephanie Klick
- March 10 - staff of the House Committee on Appropriations
- March 12 - staff of the Legislative Budget Board
- March 12 – staff of Speaker Dade Phelan
- March 15 – staff of Senator Jane Nelson
- March 31 – Senator Juan “Chuy” Hinojosa

In addition, Deputy Executive Officer and General Counsel Kristen Doyle and I video-conferenced on March 18 with Representative Senfronia Thompson regarding HB 15 and HJR 5 she filed to create the proposed Brain Institute of Texas (BITx) with a \$5 billion constitutional bond authorization modeled on CPRIT.

Compliance Program Update

Submission Status of Required Grant Recipient Reports

CPRIT has \$1.4 billion in active grants under management, with 560+ grants that are either active or wrapping up grant activities. We receive an average of 560 grantee reports each month. As of March 16, six entities had not filed 12 Academic Research reports, two Prevention reports, and four Product Development Research reports. CPRIT's grant accountants and compliance specialists review and process incoming reports and reach out to grantees to resolve filing issues. In most cases, CPRIT does not disburse grant funds until the grantee files the required reports. In some instances, grantee institutions may be ineligible to receive a future award if the grantee does not submit the required reports.

Financial Status Report Reviews

CPRIT's compliance specialists performed 270 second-level reviews of grantee Financial Status Reports (FSRs) in February and March. Twenty-five FSRs (9%) required resubmission due to insufficient or inaccurate documentation submitted by the grantee. CPRIT's grant accounting staff completes the initial review of the FSRs and supporting documentation before routing them to the compliance specialists for final review and disposition.

Single Audit Tracking

Compliance specialists track the submission of grantees' independent audit reports and the resolution of issues identified in these reports. Grantees who expend \$750,000 or more in state awards in the grantee's fiscal year must submit a single independent audit, a program specific audit, or an agreed upon procedures engagement. The grantee submits the independent audit report with findings to CPRIT within 30 days of receipt, but no later than nine months after the grantee's fiscal year end.

Currently, all grantees have submitted required audits. Grantees are unable to receive reimbursements or advances if they are delinquent in filing the required audit and corrective action plan unless the grantee requests additional time by the due date of the required audit and CPRIT's CEO approves the request.

Desk Reviews

Compliance specialists performed four enhanced desk-based financial monitoring reviews in February and March. Enhanced desk reviews verify that grantees expend funds in compliance with specific grant requirements and guidelines and may target an organization's internal controls, current and past fiscal audits, and timeliness of required grantee report submission.

Onsite Reviews

CPRIT completed seven virtual onsite reviews in February and March. Onsite reviews examine the grantee's financial and administrative operations, subcontract monitoring, inventory procedures, procurement and contracting procedures, personnel policies and procedures, payroll and timesheet policies, travel policies and records, and single audit compliance. Compliance specialists are working with one grantee to remediate onsite review findings.

Annual Compliance Attestation

CPRIT requires grantees to submit an annual Compliance Attestation form that confirms compliance with statutory and administrative grant requirements, CPRIT's policies and procedures, grant contract terms, and the Uniform Grant Management Standards. This opportunity to self-report, in the form of a checklist, provides a baseline of grantee compliance and allows compliance specialists to work proactively with grantees towards full compliance prior to a desk review or on-site review. As of March 16, all grantees have submitted their annual compliance attestations. As part of the annual attestation process, CPRIT requires Product Development grantees to submit documentation demonstrating compliance with the Texas Location Criteria pursuant to Texas Administrative Code §701.19. Compliance specialists are working with one grantee to submit the required documentation.

Training and Support

CPRIT staff conducted one new grantee training webinar in March for ImmunoGenesis, Inc. The training covered grant reporting requirements, administrative rule changes, grant closeout, and an overview of the compliance program including fraud, waste, and abuse reporting. Pursuant to Texas Administrative Code §703.22, CPRIT requires new grantees to complete the initial compliance training program prior to receiving disbursement of grant award funds.

CPRIT staff conducted a series of Annual Compliance Training webinars on March 9-11 that 220 grantee staff attended. Trainings are specific to each program area (Academic Research, Product Development Research, and Prevention) and allow for an interactive experience and opportunity to focus on topics relevant to each program. The trainings cover grant reporting requirements, administrative rule changes, grant closeout, and an overview of the compliance program including fraud, waste, and abuse reporting. This was the first training series offered this year for the annual compliance training requirement, which requires the Authorized Signing Official (ASO) and at least one other employee from each grantee organization to attend an annual compliance training by December 31 of each year.

Academic Research Program Update

FY 2021 Recruitment Applications

CPRIT's Scientific Review Council (SRC) met January 20 and March 10 to review recruitment applications submitted for cycles 21.06 - 21.08. Dr. Willson will present the SRC's recommendations to the Program Integration Committee (PIC) and the Oversight Committee in May.

FY 21.06 - 21.08 Mechanism	Received	Funds Requested	Proposed by SRC	Funds Proposed by SRC
Recruitment Established Investigators	1	\$6,000,000	1	\$6,000,000
Recruitment of Rising Stars	4	\$14,553,081	1	\$4,000,000
Recruitment of First-Time, Tenure Track Faculty Members	7	\$14,000,000	6	\$12,000,000
TOTAL	12	\$34,553,081	8	\$22,000,000

FY 2021 Review Cycle 1 - Training Applications

CPRIT received 15 applications for research training awards by the October 28, 2020, deadline. Peer reviewers met virtually on February 18 to evaluate the applications and the SRC met on March 26 to approve the award recommendations. Dr. Willson will present the SRC's recommendations to the PIC and the Oversight Committee in May.

RFA Mechanism	Received	Funds Requested	Proposed by SRC	Funds Proposed by SRC
Research Training Awards	15	\$57,385,186	8	\$30,320,920

FY 2021 Review Cycle 2 (21.2)

CPRIT released six academic research RFAs in early August and began accepting applications for the 21.2 review cycle September 16, 2020. In addition to Core Facility Support Awards, High Impact/High Risk Awards, and Early Clinical Investigator Awards, the 21.2 review cycle includes several new RFAs, including the new Clinical Trials Network Award, Texas Clinical Trials Participation Program Award, and Texas Regional Excellence in Cancer Award. Applicants submitted 159 proposals by the January 27 deadline. After peer review, Dr. Willson will present the SRC's recommended research awards to the PIC and the Oversight Committee for consideration in August.

RFA Mechanism	Received	Funds Requested
Core Facility Support Awards	25	\$95,848,572
Clinical Trials Network Awards	5	\$13,481,740
Early Clinical Investigator Awards	11	\$16,426,401
High-Impact/High Risk Awards	107	\$26,501,441
Texas Clinical Trials Participation Program Awards	4	\$5,982,538
Texas Regional Excellence in Cancer Awards	7	\$41,786,641
Total	159	\$200,027,333

Product Development Research Program Update

FY 2021 Product Development Research RFAs

CPRIT released three Product Development RFAs on November 9 seeking applications for the Texas Company, Relocation Company, and Seed Company awards. Dr. WalkerPeach and Ms. French hosted a webinar for potential applicants on November 19. CPRIT received 35 eligible applications by the January 27 deadline.

The Product Development peer review panels met by videoconference on March 22 – 23 for initial peer review. Eight companies will move forward in the peer review process for live presentations via videoconference held April 19 – 22. Dr. WalkerPeach will present the Product Development Review Council's award recommendations to the PIC and the Oversight Committee in August.

FY 2021 Grant Mechanism	Applications Received	Funds Requested	In-Person Presentations	Funds Requested
Texas Company	8	\$99,869,430	3	\$41,849,848
Relocation Company	6	\$97,956,112	2	\$35,568,812
Seed Company	21	\$55,118,837	3	\$8,988,950
TOTAL	35	\$252,944,379	8	\$86,407,610

Prevention Program Update

FY 2021 Cycle 1 (21.1) Prevention Review Cycle

CPRIT released the *Expansion of Cancer Prevention Services to Rural and Medically Underserved Populations* RFA on August 3 for the first review cycle of FY 2021. CPRIT's prevention peer review panels convened via videoconference on January 19 - 20 to review the 12 applications requesting \$26,133,587 in grant funds. The Prevention Review Council (PRC) met

March 4 to consider the applications. Ms. Magid will present the PRC's five grant award recommendations totaling \$11.2 million to the PIC and the Oversight Committee in May.

FY 2021 Cycle 2 (21.2) Prevention RFAs

CPRIT released four 21.2 RFAs (listed below) in October 2020. CPRIT received 22 applications requesting \$24.5 million by the February 10 deadline. Peer review will take place April 26-29 and Ms. Magid will present the PRC's 21.2 recommendations to the PIC and the Oversight Committee in August.

21.2 Grant Mechanism	Received	Funds Requested
Dissemination of CPRIT-Funded Cancer Control Interventions	4	\$ 1,198,638
Evidence-based Cancer Prevention Services	10	\$ 9,724,716
Expansion of Cancer Prevention Services to Rural and Medically Underserved Populations	3	\$ 6,580,487
Tobacco Control and Lung Cancer Screening	5	\$ 6,973,002
TOTAL	22	\$24,476,843

FY 2021 Prevention Program RFAs

- Dissemination of CPRIT-Funded Cancer Control Interventions*
 Seeks to fund projects that will facilitate the dissemination and implementation of successful CPRIT-funded, evidence-based cancer prevention and control interventions across Texas. The proposed project should be able to develop one or more "products" based on the results of the CPRIT-funded intervention. The proposed project should also identify and assist others to prepare to implement the intervention and/or prepare for grant funding.
 Award: Maximum of \$300,000 over 24 months.
- Evidence-Based Cancer Prevention Services*
 Seeks projects that will deliver evidence-based cancer prevention and control clinical services. CPRIT will give priority to projects that propose to address CPRIT areas of emphasis and serve areas of the state not well addressed by current CPRIT funded projects.
 Award: Up to \$1 million over 36 months.
- Tobacco Control and Lung Cancer Screening*
 Seeks programs on tobacco prevention and cessation, as well as screening for early detection of lung cancer. Through release of this RFA, CPRIT's goal is to stimulate more programs across the state, thereby providing greater access for underserved populations and reducing the incidence and mortality rates of tobacco-related cancers. This RFA seeks to promote and deliver evidence-based programming designed to significantly increase tobacco cessation among adults and/or prevent tobacco use by youth.
 New Award: Up to \$1 million over 36 months.

Expansion Award: Up to \$2.5 million over 3 years.

- *Expansion of Cancer Prevention Services to Rural and Medically Underserved Populations*
Seeks to support coordination and expansion of evidence-based services to prevent cancer in underserved populations who do not have adequate access to cancer prevention interventions and health care, bringing together networks of public health and community partners to carry out programs tailored for their communities. Projects should identify cancers that cause the most burden in the community and use evidence-based models shown to work in similar communities to prevent and control these cancers. Currently funded CPRIT projects should propose to expand their programs to include additional types of prevention clinical services and/or an expansion of current clinical services into additional counties. In either case, the expansion must include delivery of services to nonmetropolitan and medically underserved counties in the state.

Initial Expansion Award: Up to \$2 million over 3 years.

Subsequent Expansion Award: Up to \$2.5 million over 5 years.

Advisory Committee Meetings

Several advisory committees met in March or plan to meet in April to prepare for annual presentations to the Oversight Committee on May 19. All meetings are via videoconference.

- The University Advisory Committee met March 2
- The Advisory Committee on Childhood Cancers met March 5
- The Product Development Advisory Committee will meet April 14

Operations, Audit and Finance Update

State Auditor's Office Audit

The State Auditor's Office (SAO) audit team continued the planning phase of the grant management audit through the beginning of March. During the week of March 15, the audit team ended the planning phase and switched to conducting field work. The SAO plans to finish field work by May 14.

Request for Proposals

- CPRIT issued a competitive request for proposals (RFP) for grant management support services on February 25 after addressing some procurement requirements raised during the required review by the Contract Advisory Team (CAT). CAT is a statewide procurement review committee that assesses RFP documents for risk mitigation when the expected contract will exceed \$5 million. The RFP is necessary to continue the grant management support services for fiscal year 2022 and beyond. CPRIT will evaluate proposals received by

the March 29 deadline and provide a recommendation for approval by the Oversight Committee.

- On February 8 CPRIT issued a request for proposals for financial audit services. CPRIT exercised our final renewal on the current contract this year with McConnell & Jones, the incumbent firm. CPRIT received five proposals in response to this RFP by the March 8 due date; we will provide a recommendation for Oversight Committee approval.

Grant Expenses Related to COVID-19

CPRIT did not pay any COVID-related expenses on FSRs during the months of January and February. Grantee claims for these expenses have slowed down significantly. Through the end of February, CPRIT has reimbursed \$3,340,970 in total COVID-related expenses claimed by grantees.

The Legislative Budget Board announced in January that it no longer requires agencies to report this expense information to them monthly.

Transfer to Address FY 2021 SWCAP

The Comptroller Office's notified CPRIT in early January of a 552% increase in CPRIT's fiscal year 2020 Statewide Cost Allocation Plan (SWCAP) amount. The 2020 charge is based on state expenditures and state agencies' use of central state services in fiscal year 2018. CPRIT requested the Governor's Office verify the calculation because of the significant increase. The Governor's Office confirmed the amount March 17, explaining that the increase reflects CPRIT use of the state's Centralized Accounting and Payroll/Personnel System (CAPPS) Financial module for our accounting and procurement processes. CPRIT started using CAPPS in fiscal year 2018.

CPRIT will not have sufficient unused budget in fiscal year 2021 to accommodate the increased SWCAP this year. Therefore, as discussed at the February 17 Oversight Committee, on March 26 I requested from the Legislative Budget Board (LBB) a transfer in fiscal year 2021 from CPRIT's research and prevention line items of appropriations to indirect administration. Because the ongoing legislative session is consuming the LBB's attention, I do not expect approval of this request until sometime over the summer.

Going forward, CPRIT will continue to use the CAPPS module so we must plan for this higher SWCAP allocation. As I noted earlier in this update, CPRIT added the \$450,000 SWCAP transfer from the research and prevention programs to indirect administration as an exceptional item request for CPRIT's proposed budget for fiscal years 2022 and 2023. The Senate Finance Committee and the House Appropriations Committee have both added the SWCAP exceptional item request to the proposed appropriations bills currently working their way through the legislature.

Communications Update

Media Highlights

- The *Houston Business Journal* featured Iterion and the company's \$17 million funding round to support clinical trials.
- The *San Antonio Express-News* highlighted UT Health San Antonio's latest CPRIT recruitment award for Alexander Mazin.
- CPRIT Scholar Dr. Sean Morrison's research into how exercise strengthens bones and the immune system was the subject of an article in *The Scientist*.
- Bio-Techne's acquisition of CPRIT grantee Asuragen received media attention in various publications, including the *Austin Business Journal*, *Twin Cities Business Journal* and the *Minneapolis Star-Tribune*.
- The *Dallas Morning News* mentioned CPRIT's funding of the Sauer Lab in an article about UT Austin's COVID-19 research.

2/22/21 – “Houston oncology co. Iterion Therapeutics raises \$17M for clinical trials” – *Houston Business Journal* <https://www.bizjournals.com/houston/news/2021/02/22/houston-oncology-co-raises-17m-for-clinical-trials.html>

02/27/21 – “UT Health San Antonio gets \$6 million grant for DNA cancer research from state agency” – *San Antonio Express-News* <https://www.expressnews.com/news/local/article/UT-Health-San-Antonio-gets-6-million-grant-for-15985067.php>

03/02/21 – “Impact of Running Reaches Marrow to Spark Bone Growth in Mice”- *The Scientist* <https://www.the-scientist.com/news-opinion/impact-of-running-reaches-marrow-to-spark-bone-growth-in-mice-68504>

03/04/21 – “Minneapolis-based Bio-Techne buying Texas company for at least \$215M” – *Minneapolis Star-Tribune* <https://www.startribune.com/minneapolis-based-bio-techne-buying-texas-company-for-at-least-215m/600030169/>

03/12/21 – “Breakthrough research at UT Austin is protecting the world against COVID-19”- *Dallas Morning News* <https://www.statesman.com/story/business/2021/01/13/3-billion-proposed-texas-based-research-stop-future-pandemics/6579500002/>

Media Relations

CPRIT announced that Tracey Davies joined as CPRIT's new Chief Strategic Initiatives and Intellectual Property Officer via press release on March 1. *Quorum Report's* “People on the Move” and *Texas Government Insider* both carried excerpts that week.

On March 23, CPRIT distributed a press release highlighting encouraging signs of recovery in the uptick of cancer screenings and emphasizing the importance of routine cancer screenings. Organizations that provide cancer screenings funded by CPRIT reported a precipitous decline in the number of Texans receiving routine cancer screenings in 2020 due to the COVID-19 pandemic. The *El Paso Herald-Post* carried CPRIT's report on that same day.

Social Media

CPRIT promoted the March 9 panel "Science Sparks: Big Strides in Fighting Cancer" featuring Nobel Laureate Dr. James Allison and Dr. Livia Eberlin and moderated by Dr. Willson.

In conjunction with Colorectal Cancer Awareness Month, CPRIT featured grantees' work in colorectal cancer. We also used social media to highlight International HPV Awareness Day (March 4) and World Kidney Day (March 11).

April is Minority Cancer Awareness Month. CPRIT is working with State Representative Toni Rose's office and the Moncrief Cancer Institute to create a series of videos for social media around this subject. We will interview Rep. Rose and two patients from Moncrief.

Social Media Statistics

- Twitter (February 25 - 24)

Total Tweets: 15

Tweet Impressions: 28,800

Profile Visits: 854

Mentions: 25

New Followers: 30 (2,797 total)

Top tweet: Dr. James Willson, [#CPRIT](#) Chief Scientific Officer, will moderate "Science Sparks: Big Strides in Fighting Cancer" with Nobel Laureate Dr. James Allison of [@MDAndersonNews](#) and [@livia_se](#) of [@TexasScience](#) at the [#TXScienceFest](#) next Tuesday 3/9. For details: cprit.us/3rm9rLM

Impressions: 8,638

Engagements: 194

Top mention: @emacalate - Congratulations to an amazing Mack and Deneen Lab team effort led by Amir Arabzade, Yanhua Zhao, Srinidhi Varadharajan, and Eileen Chen! Thank you also [@AlexsLemonade](#) [@CPRITTexas](#) for your support of pediatric brain tumor research!

Engagements: 310

- LinkedIn (February 21 – March 23)

Total Updates: 16

Post Impressions: 3,500
Reactions: 83
Shares: 6
Page views: 80
Unique Visitors: 42
New followers: 13 (1107 total)

Top Update: Dr. James Willson, [#CPRIT](#) Chief Scientific Officer, will moderate "Science Sparks: Big Strides in Fighting Cancer" with Nobel Laureate and CPRIT [#Scholar](#) Dr. James Allison of [MD Anderson Cancer Center](#) and CPRIT grantee Dr. Livia Eberlin of [The University of Texas at Austin](#) at the [#TXScienceFest](#) next Tuesday, March 9th. For details and registration, visit here: <https://t.co/3wQo9EjXbZ>
Impressions: 290
Clicks: 12
Reactions: 10
Engagement rate: 7.93 %

- Facebook (February 24 – March 23)

Reach: 548 people
Engagement: 111 reactions/clicks
Page Views: 87

Top Post: March is [#ColorectalCancerAwarenessMonth](#). Learn how CPRIT helped establish the Community Network for Cancer Prevention (CNCV), a partnership between [Baylor College of Medicine](#) and [Harris Health System](#) that has impacted [#colorectalcancer](#) screening rates through linguistically and culturally targeted, entertainment-based cancer screening education to the African American, Hispanic, and Vietnamese medically underserved communities: <http://cprit.us/3pM0F93>
Post Reach: 281 people
Engagement: 5 clicks, 11 reactions, 2 shares

Upcoming Subcommittee Meetings

Listed below are the subcommittee meetings in advance of the May 19, 2021, Oversight Committee meeting.

Board Governance	May 6 at 10:00 a.m.
Audit	May 10 at 10:00 a.m.
Prevention	May 11 at 10:00 a.m.
Academic Research	May 12 at 10:00 a.m.
Product Development	May 13 at 10:00 a.m.
Nominations	May 14 at 10:30 a.m.

We will send instructions for signing onto the Zoom platform along with the subcommittee agenda and meeting materials one week prior to the meeting date. Please plan to join the subcommittee meeting a few minutes early so we can address any technology issues before the meeting start time.

CPRIT has awarded **1,585** grants totaling **\$2.669 billion**

- 244 prevention awards totaling \$277.7 million
- 1,341 academic research and product development research awards totaling \$2.392 billion

Of the \$2.392 billion in academic research and product development research awards,

- 30.5% of the funding (\$730.0 million) supports clinical research projects
- 24.4% of the funding (\$582.0 million) supports translational research projects
- 28.9% of funding (\$691.6 million) supports recruitment awards
- 13.7% of the funding (\$327.7 million) supports discovery stage research projects
- 2.5% of funding (\$60.0 million) supports training programs.

CPRIT has 8 open Requests for Applications (RFAs)

- 3 Research Recruitment
- 5 Academic Research



CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

MEMORANDUM

TO: OVERSIGHT COMMITTEE MEMBERS
FROM: WAYNE R. ROBERTS, CHIEF EXECUTIVE OFFICER
SUBJECT: CPRIT ACTIVITIES UPDATE FOR APRIL
DATE: MAY 3, 2021

Topics in this memo address CPRIT activities in April, including the upcoming May 19 Oversight Committee meeting, recent milestones in the fight against cancer, a staffing summary, a legislative update, outreach efforts, and news from Compliance, Programs, and Operations.

Planning for the May 19 Oversight Committee Meeting

The Oversight Committee will meet May 19 using the Zoom platform. CPRIT will post the final agenda for the Oversight Committee meeting by May 11. Please notify me if you are unable to attend the May 19 meeting or have schedule constraints that require you to join the meeting after 9:00 a.m. or leave prior to 11:30 a.m. Oversight Committee members will receive an electronic copy of the meeting book by May 12; we will also mail you a hard copy of the meeting book and proposed award packet.

CPRIT will send you an email by May 7 with a link and password to access the Program Integration Committee's academic research and prevention program award recommendations via the grant award portal. The portal has a summary of the award slates, as well as supporting documentation for each proposed award, including the application, CEO affidavit, summary statement, and grant pedigree. Please allow some time to complete the individual conflict of interest checks and review the supporting material.

You will receive an email from CPRIT with information unique to you for signing onto Zoom. (This is different than the sign-on information provided for the public listed on the published Oversight Committee agenda.) Plan to sign on 15 minutes before the 9:00 a.m. start time so that we can address any connection issues without delaying the meeting.

Recent Milestones in the Fight Against Cancer

CPRIT Grantees in the News

- Austin-based Aeglea Biotherapeutics, Inc. announced March 22 a commercialization agreement with Immedica Pharma AB for pegzilarginase for the treatment of arginase 1 deficiency in Europe and the Middle East. Under the terms of the agreement, Immedica will make an upfront payment of \$21.5 million to Aeglea. Additionally, Aeglea will be eligible to

receive up to approximately \$130 million in regulatory and commercial milestones as well as royalties on net sales. Immedica receives commercialization rights in Europe and several Middle East countries. Aeglea continues responsibilities for certain clinical development activities and manufacturing of pegzilarginase and retains commercialization rights in the U.S. and rest of the world.

Aeglea received a \$19.8 million CPRIT Product Development Research award (DP140031) in 2014 to develop an engineered human arginase targeting multiple cancer types.

- On March 29 the American Association for Cancer Research (AACR) announced the induction of CPRIT grantee Guillermina Lozano, Ph.D., professor and chair, Department of Genetics at The University of Texas MD Anderson Cancer Center, into the 2021 class of Fellows of the AACR Academy. She was one of 25 new Fellows recognized by AACR for remarkable and crucial contributions to cancer research. Dr. Lozano was the first to establish p53 as a transcriptional activator of other genes. P53 is a tumor suppressor gene that, when neutralized, plays a critical role in the development of many types of tumors. She is a member of the National Academy of Sciences, elected in 2017. CPRIT has awarded four individual investigator research awards to Dr. Lozano to investigate the p53 tumor suppressor pathway role in liver cancer (RP200240), triple negative breast cancer (RP180313, RP100535), and osteosarcoma and pancreatic cancer (RP170231).
- Perimeter Medical Imaging AI, Inc. announced March 30 that Northern Arizona Healthcare Verde Valley Medical Center expects to enroll up to 100 patients in a study to evaluate the use of Perimeter's Optical Coherence Tomography (OCT) Imaging System during breast conserving surgery.

Perimeter created the OCT Imaging System to use as an imaging tool in the evaluation of excised human tissue microstructure by providing two-dimensional, cross-sectional, real-time depth visualization with image review manipulation software for identifying and annotating regions of interest. The company, based in Dallas and Toronto, is also making significant progress within its ATLAS AI Project, an initiative aimed at advancing Perimeter's next-gen artificial intelligence (AI) and machine learning tools through clinical development. Perimeter has trained its proprietary "ImgAssist" AI technology with more than 400 volumes of images of excised breast tissue collected during the first stage of its ATLAS AI project.

In April, the U.S. Food and Drug Administration granted the company a Breakthrough Device Designation for the OCT Imaging System coupled with ImgAssist AI. This designation allows for accelerated interactions with the FDA during product development and prioritized review of future regulatory submissions.

Perimeter received a \$7.4 million CPRIT Product Development Research award (DP190087) in 2019 to develop an optical tissue imaging system for breast conserving surgery.

- Molecular Templates, Inc. announced April 5 that the company has decided to discontinue development of drug candidate MT-3724 to focus its resources on developing next-

generation Engineered Toxin Bodies (ETBs.) The Austin-based company also announced that following discussion with its co-development partner Takeda, Molecular Templates will assume full rights to TAK-169, including taking control of clinical development.

Molecular Templates has received two CPRIT Product Development awards to date, including a \$10.6 million award (CC121020) in 2011 to develop novel targeted ETBs to treat lymphoma, and a \$15.2 million award (DP160071) in 2016 to develop a novel compound to treat multiple myeloma.

- Nicholas E. Navin, Ph.D., associate professor in the Department of Genetics at The University of Texas MD Anderson Cancer Center, and director of the CPRIT Single Cell Genomics Center (RP1806840), received the 2021 AACR Award for Outstanding Achievement in Basic Cancer Research on April 8 for his seminal contributions to the understanding of genome evolution and intratumor heterogeneity in breast cancer.

The award recognizes Dr. Navin for his invention of single-cell DNA sequencing, which has impacted many diverse fields of biology and biomedicine and has directly contributed to establishing the single-cell genomics field. Single cell sequencing is a revolutionary new technology that can provide genomic information on individual cancer cells. Previous sequencing technologies limited analysis to bulk tissue, which reports an average signal from a complex mixture of millions of cells in the tumor. Bulk tissue analysis is problematic, since tumors consist of many diverse cell types (e.g., blood vessels, fibroblasts, immune cells) that are intermixed with different tumor clones that harbor diverse mutational patterns. In these bulk data sets, researchers lose important information on rare subpopulations that may play an important role in tumor progression.

- Iterion Therapeutics, Inc. recently completed enrollment and dosed the final patient in its multicenter Phase 1/2a dose expansion clinical study of Tegavivint in patients with desmoid tumors. The company announced April 13 that the expansion study confirmed the safety of Tegavivint, a novel, potent and selective nuclear beta-catenin inhibitor. Houston-based Iterion received a \$15.9 million CPRIT Product Development Research award (CP130058) in 2014 to develop Tegavivint for desmoid tumors and acute myeloid leukemia.
- The American Society of Mechanical Engineers (ASME) named CPRIT Scholar in Cancer Research B.J. Fregly, Ph.D., as an ASME fellow on April 21 in honor of his significant engineering achievements. Rice University recruited him to Texas in 2017 with a \$5 million CPRIT Established Investigator recruitment grant (RR170026.) Dr. Fregly, professor of mechanical engineering and bioengineering at Rice University, has received numerous research grants from the National Institutes of Health and the National Science Foundation, including a CAREER Award.

Dr. Fregly's lab uses computational modeling and simulation of the human neuromusculoskeletal system to design improved surgical and rehabilitation treatments for movement impairments caused by cancer, stroke, and osteoarthritis. His CPRIT project, a collaboration with MD Anderson, is to design optimized surgical treatment plans and custom

pelvic implants that maximize post-surgery walking ability for individuals with pelvic cancer. His research team first builds a neuromusculoskeletal computer model of the patient using movement data collected prior to surgery, and then performs virtual treatments on the patient's model to identify the best treatment approach for that patient – a novel example of personalized medicine.

- Medicenna Therapeutics, Corp. appointed Kevin Moulder, Ph.D., as the Company's Chief Scientific Officer on April 21. Houston and Toronto-based Medicenna Therapeutics, Corp. received a \$14.1 million CPRIT Product Development award in 2014 to develop MDNA455, a novel immunotherapy to treat recurrent glioblastoma and other brain cancers.
- AACR will present Carol L. Prives, Ph.D., with the *2021 AACR-G.H.A. Clowes Award for Outstanding Basic Cancer Research* during the AACR Annual Meeting 2021 in May. Dr. Prives is a member of CPRIT's Scientific Review Council and the Da Costa Professor of Biology at Columbia University. She is an elected member of the National Academy of Sciences (2008) and the Institute of Medicine (2005) and is an elected fellow of the American Academy of Microbiology (2001) and the American Academy of Arts and Sciences (2000).

Dr. Prives' remarkable achievements have earned her many awards and accolades, including the NIH Outstanding Investigator Award (2018), the Paul Janssen Prize in Biotechnology and Medicine (2010), the NCI Rosalind E. Franklin Award for Women in Science (2009), the American Cancer Society Research Professorship (1998), and the NIH MERIT Award (1996). AACR is recognizing Dr. Prives for discovering that p53 is a DNA sequence-specific transcriptional activator that possesses novel oncogenic functions when mutated, as well as for her work involving the identification of stress signal-induced regulatory mechanisms of p53 and Mdm2 and for revealing novel pathways by which p53 functions to suppress cell growth and promote cell death.

- The National Academy of Sciences announced on April 29 the election of multiple-CPRIT grantee Jonathan Sessler, Ph.D., to its membership. The academy is the country's most prestigious scientific organization, and election to it is one of the highest honors for American researchers. Dr. Sessler holds the Roland K. Pettit Centennial Chair in Chemistry in the College of Natural Sciences at The University of Texas at Austin. Specializing in the engineering of molecules, Dr. Sessler - a two-time cancer survivor - developed a class of experimental drugs that target cancerous tumors, helping to earn him previous election to the National Academy of Inventors. Dr. Sessler has received more than \$4 million in CPRIT research grants (RP120393, RP140108, and DP150087) as well as a \$2.5 million CPRIT research training grant award (RP101501).

Notable CPRIT-Supported Research Accomplishments

- New research led by CPRIT Scholar Jian Xu, Ph.D., associate professor of pediatrics at The University of Texas Southwestern Medical Center, has uncovered a surprising role for so-called jumping genes. The jumping genes, also known as transposons, are a source of

genetic mutations responsible for several human diseases. Transposons are DNA sequences that can jump from one location in the genome to another when activated. Activation of transposons often leads to mutations that can cause cancer. The new study, published April 8 in the journal *Nature Genetics*, reported that activation of a particular type of transposon can protect against certain blood cancers. The discovery may provide a mechanistic explanation for the unusual sensitivity of myeloid leukemia cells to DNA damage-inducing therapies that oncologists currently use to treat patients. CPRIT awarded four grants to support this work (RR140025, RP180504, RP180826 and RP190417).

- Researchers at The University of Texas MD Anderson Cancer Center have discovered that mutant KRAS and p53, the most frequently mutated genes in pancreatic cancer, interact through the CREB1 protein to promote metastasis and tumor growth. Blocking CREB1 in preclinical models reversed these effects and reduced metastases, suggesting an important new therapeutic target for the deadly cancer. CPRIT research grant RP170231 provided support for the project findings, published online April 10 in the journal *Cancer Discovery* and presented at the 2021 AACR Annual Meeting.
- Hummingbird Bioscience, Inc. presented pre-clinical data on its BCMA-TACI dual-specific T cell engager, HMBD-009, at the 2021 American Association for Cancer Research (AACR) Annual Meeting on April 13. The company, based in Houston, San Francisco, and Singapore, received a \$13.1 million CPRIT Product Development award (DP190027) in 2019 to develop a first-in-class anti-VISTA monoclonal antibody to treat MDSC-mediated suppression of anti-tumor immunity in solid tumors and lymphomas.

Personnel

CPRIT has filled 34 of our 36 full-time equivalent (FTE) positions.

Chief Scientific Officer Search

CPRIT released the job description posting on April 2. Spencer Stuart, the company assisting us in this search, expects a final list of candidates by May 24. Candidate interviews will take place in June and July. I will update the Oversight Committee as developments warrant.

CPRIT Outreach

Staff outreach activities during April include:

- Senior Program Manager for Product Development Rosemary French attended the *2021 Spring Oncology Investor Conference*, a virtual event held March 29 through April 2 and sponsored by the National Foundation for Cancer Research.
- Ms. French participated in the *2021 Health Innovations Power Pitch Competition*, a virtual event held April 8 and hosted by The University of Texas at Austin for graduate student teams to present their ideas for improving the patient experience in healthcare.

- Chief Scientific Officer Dr. Jim Willson, Chief Product Development Officer Dr. Cindy WalkerPeach, and Chief Prevention Officer Ramona Magid attended the 2021 American Association for Cancer Research (AACR) Annual meeting, held virtually April 12-15. AACR is the world's oldest and largest professional associated related to cancer research.
- Several staff members met with cancer advocates via videoconference on April 18 to discuss pending legislation that affects CPRIT.
- Dr. Willson and Oversight Committee member Dr. Bill Rice cohosted a discussion on April 21 with CPRIT-funded experts in computational biology, including CPRIT Scholars Thomas Yankeeelov, Ph.D., Gaudenz Danuser, Ph.D., and Traver Hart, Ph.D. The meeting participants discussed computational oncology and systems biology, including opportunities for CPRIT to establish Texas as a global leader and accelerate progress in this area of cancer research. Oversight Committee members Dr. Mahendra Patel and Will Montgomery participated in the discussion as well as several CPRIT staff.
- Ms. Magid attended the CDC Prevention Research Centers Virtual Meeting: "Re-imagining Prevention Science During Unprecedented Times," held April 27 – 29.

Legislative Session Update

The 87th Texas Legislature will adjourn *Sine Die* at midnight May 31. The legislative pace has picked up and developments occur daily. The information reported below on CPRIT's budget, CPRIT-related legislation, other notable legislation is current as of 9:00 a.m., May 3. I will notify you regarding any notable legislative action.

General Appropriations Bills (Senate Bill 1 and House Bill 1)

Summary of CPRIT's Exceptional Items Budget Request

Exceptional Item Request	HB 1 filed	HAC subcomm	Full HAC	House	SB 1 filed	SFC subcomm	Full SFC	Senate
Base Adjustment for Ongoing Operating Costs	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes
8 New FTE Positions	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Budget Transfer Authority	Partial	Partial	Partial	Partial	Yes	Yes	Yes	Yes
CSO Exempt Salary Increase	No	Pend	Pend	Pend	No	Yes	Yes	Yes
SWCAP Base Adjustment	No	Yes	Yes	Yes	No	Yes	Yes	Yes

CPRIT is in an extremely favorable position regarding agency appropriations for fiscal years 2022-2023. Both chambers adopted versions of the general appropriations bill that provide full appropriations for CPRIT and include most (House Bill 1) or all (Senate Bill 1) of CPRIT's

requested exceptional items, including eight new full time equivalent (FTE) positions and the SWCAP base adjustment. The only two exceptional item issues to resolve by the budget conference committee are the Chief Scientific Officer exempt salary increase and CPRIT's transfer authority. These recommendations are a definite sign of confidence in CPRIT and indicate the legislature's strong faith in the agency, our mission, and your leadership.

Background Regarding Budget Approval Process

The House and Senate released their general appropriations bills January 21. Both Senate Bill 1 (SB 1) and House Bill 1 (HB 1) as introduced provided CPRIT's full, constitutionally authorized annual appropriation of \$300 million less the required transfer of \$3.1 million per year to the Cancer Registry at the Texas Department of State Health Services. Unlike many state agencies, state leadership did not instruct CPRIT to make any reductions from its base request for 2022 and 2023. As reflected in the table above, SB 1 as introduced included several of CPRIT's requested changes. HB 1 as introduced took a more traditional approach, carrying forward CPRIT's previous appropriations with minimal adjustments.

The Senate Finance Committee (SFC) and the House Appropriations Committee (HAC) and their respective subcommittees held public hearings in February and March and worked with the budget analysts from the Legislative Budget Board (LBB) to review the budget recommendations for each agency. Ms. McConnell and I presented CPRIT's budget request to the Senate Committee on Finance on February 9 and to the House Committee on Appropriations Subcommittee on Articles I, IV and V on March 1.

On March 8, the Senate Finance Workgroup on Articles I, IV and V (Senators Huffman (chair), Campbell, Schwertner, Whitmire) released initial recommended changes to SB 1. The House Appropriations Subcommittee on Articles I, IV and V (Representatives M. González (chair), Ashby, Holland, Schaefer, Sherman) marked up CPRIT on March 17. Both subcommittees made recommendations to their full committees in CPRIT's favor. The full committees for the SFC and the HAC adopted their respective subcommittee's mark ups for CPRIT on March 24 (SFC) and March 30 (HAC).

The two chambers approved their version of the budget bills on April 6 (Senate) and April 22 (House). Each chamber designated members to negotiate the differences between the two bills. Senate conference committee members are: Senators Nelson (chair), Huffman, Kolkhorst, Nichols, and Taylor. The House conference committee members are Representatives Bonnen (chair), Capriglione, M. González, Walle, and Wilson. This budget conference committee will present the negotiated appropriations bill to each chamber for final approval, likely in late May.

Budget Transfer Authority

Currently, the LBB (specifically the Chairs of HAC and SFC, the Lieutenant Governor, and the Speaker) must each individually approve a CPRIT transfer request before the agency may transfer appropriated funds between budget line items. These transfer requests are non-controversial but necessary to maintain operational stability. However, because of the multiple

signoffs required for approval, CPRIT's budget transfer requests have languished administratively for months, with a recent request taking 115 days to get approved.

The Senate tracks our request by authorizing CPRIT's CEO, with Oversight Committee acknowledgement, to transfer up to 20 percent from one line item to another. Although CPRIT must report the transfer to the LBB, the Senate does not require additional approval before the transfer may occur. This is the standard budget transfer provision for most state agencies.

The House takes a different approach. It proposes limiting the window for rejecting CPRIT's budget transfer request to 30 days. Unless the HAC Chair, SFC Chair, the Lieutenant Governor or the Speaker specifically reject CPRIT's request, CPRIT may make the budget transfer on the 31st day. The House's proposed change is a significant improvement over CPRIT's current provision, but still treats CPRIT differently from most state agencies.

CPRIT-Related Legislation

- [Senate Bill 74/House Bill 4241](#) (companions)
Senator Borris Miles and Representative Jacey Jetton filed legislation amending CPRIT's statute (Tex. Health & Safety Code §102.255(d)) to allow research institutions or their affiliated centers to use the federal indirect rate as a credit to offset CPRIT's matching requirement. The credit is already available to institutions of higher education as defined by the Texas Education Code, but the amendment addresses the research institutions that do not qualify under Education Code designation.

Last action: HB 4241 referred to House Public Health Committee; the Senate Committee on Health & Human Services took testimony on SB 74 on April 28 and left the bill pending.

- [Senate Bill 713/House Bill 1860](#) (companions)
Representative John Cyrier and Senator Dawn Buckingham, in their respective roles as Chair and Vice Chair of the Sunset Commission, each introduced legislation to reorder several upcoming agency sunset reviews. The proposed legislation changes CPRIT's sunset review date from 2023 to 2029.

Last action: The Senate unanimously passed SB 713 on April 19 and the Speaker of the House referred the bill to the House State Affairs Committee. On April 29, the House State Affairs Committee reported SB 713 favorably out of committee. The bill will now go to the House Calendars Committee for placement on an upcoming House agenda for consideration.

- [Senate Bill 1563/House Bill 3579](#) (companions)
Senators Juan "Chuy" Hinojosa and Eddie Lucio and Representative R.D. "Bobby" Guerra filed companion legislation that makes significant changes to CPRIT's enabling legislation.

One proposed change would allow the Oversight Committee to consider and approve any application for grant awards, even those applications not recommended after peer review. If the Oversight Committee does not vote to approve a grant application that a member pulls

from the list of non-recommended applications for consideration, then the Oversight Committee must record its reasoning for not approving the award(s) in the minutes of the meeting. Currently, the Program Integration Committee and the Oversight Committee may only consider applications reviewed and recommended by the peer review panels for grant awards.

The second proposed change appears to alter the way that prevention grant funds would be allocated by requiring that CPRIT give the funding to specified counties rather than project leaders, even if there is no apparatus in the county to complete the project. The same section contains an unclear requirement that CPRIT fund projects in medically underserved areas with a health-related institution whose expenditure for research and development is not in the top three among health-related institutions and has a hospital; however, this money can only go to prevention “programming and operations.”

The third proposed change would allow CPRIT to award any grant funds recovered from awards failing to meet the terms and conditions of their contracts to other projects in “the same grant cycle that CPRIT deems able to be “imminently commenced.”

In addition to these three significant changes, the proposed legislation adds The University of Texas Rio Grande Valley School of Medicine to the list of universities from which the chancellor of The University of Texas System must choose two representatives to represent the system on CPRIT’s University Advisory Committee.

Last action: Referred to Senate Health & Human Services, House Public Health Committees

- [House Bill 2252](#)
Representative Oliverson filed legislation that would prohibit CPRIT from awarding a grant to an applicant that plans to buy organs from a hospital in China. The bill also requires CPRIT to add a written contract certification that the grantee will not use grant funds to buy organs from a hospital in China for all awards, including those made prior to the effective date of the bill. On March 15 I discussed Mr. Oliverson’s concerns with his staff. Based on this discussion we provided alternative language that should address the representative’s concerns in a way that minimizes administrative burdens on CPRIT.

Last action: Referred to House Public Health

Other Notable Legislation

- [House Joint Resolution 5](#) and [House Bill 15](#)
Representative Senfronia Thompson filed legislation to create the Brain Institute of Texas. The House Higher Education Committee adopted the committee substitutes for HJR 5 and HB 15. The House approved HJR 5 on April 27 by a vote of 114 Yeas, 33 Nays, and 1 Present, not voting; the House approved HB 15 on April 28 by a vote of 107 Yeas, 36 Nays, and 1 Present, not voting. The Speaker of the House will send legislation to the Senate for assignment to a Senate committee.

- [Senate Joint Resolution 17](#) and [Senate Bill 264](#)
Senator Jose Menéndez filed legislation to create the Texas Research Consortium to Cure Infectious Diseases (TRANSCEND) with a \$3 billion constitutional bond authorization. Senator Menéndez explained that he intends CPRIT to serve as a model for the new agency. The Lt. Governor referred the proposed legislation to the Senate Health & Human Services Committee. The committee has not scheduled a hearing on the proposed legislation.

Testimony and Legislative Outreach

- On April 13 Deputy Executive Officer and General Counsel Kristen Doyle and I met with Representative R.D. “Bobby” Guerra to discuss his House Bill 3579.
- On April 26 I discussed CPRIT’s budget conference committee priorities with staff of the Lt. Governor, Senator Nelson, and the House Committee on Appropriations.
- I discussed pending legislation affecting CPRIT and our budget conference committee priorities with staff of the Speaker of the House.
- Ms. Doyle and I testified as resource witnesses at the April 28 Senate Health and Human Services Committee hearing on SB 74.

Compliance Program Update

Submission Status of Required Grant Recipient Reports

CPRIT has \$1.4 billion in active grants under management, with 560+ grants that are either active or wrapping up grant activities. We receive an average of 560 grantee reports each month. As of April 22, five entities had not filed three Academic Research reports and five Product Development Research reports. CPRIT’s grant accountants and compliance specialists review and process incoming reports and reach out to grantees to resolve filing issues. In most cases, CPRIT does not disburse grant funds until the grantee files the required reports. In some instances, grantee institutions may be ineligible to receive a future award if the grantee does not submit the required reports.

Financial Status Report Reviews

CPRIT’s compliance specialists performed 131 second-level reviews of grantee Financial Status Reports (FSRs) in April. Eleven FSRs (8%) required resubmission due to insufficient or inaccurate documentation submitted by the grantee. CPRIT’s grant accounting staff completes the initial review of the FSRs and supporting documentation before routing them to the compliance specialists for final review and disposition.

Single Audit Tracking

Compliance specialists track the submission of grantees' independent audit reports and the resolution of issues identified in these reports. Grantees who expend \$750,000 or more in state awards in the grantee's fiscal year must submit a single independent audit, a program specific audit, or an agreed upon procedures engagement. The grantee submits the independent audit report with findings to CPRIT within 30 days of receipt, but no later than nine months after the grantee's fiscal year end.

Currently, all grantees have submitted required audits. Grantees are unable to receive reimbursements or advances if they are delinquent in filing the required audit and corrective action plan unless the grantee requests additional time by the due date of the required audit and CPRIT's CEO approves the request.

Desk Reviews

Compliance specialists performed three enhanced desk-based financial monitoring reviews in April. Enhanced desk reviews verify that grantees expend funds in compliance with specific grant requirements and guidelines and may target an organization's internal controls, current and past fiscal audits, and timeliness of required grantee report submission. Compliance specialists are working with one grantee to remediate enhanced desk review findings.

Onsite Reviews

CPRIT completed six virtual onsite reviews in April. Onsite reviews examine the grantee's financial and administrative operations, subcontract monitoring, procurement and contracting procedures, inventory procedures, personnel policies and procedures, payroll and timesheet policies, travel policies and records, and single audit compliance. Compliance specialists are working with one grantee to remediate onsite review findings.

Annual Compliance Attestation

CPRIT requires grantees to submit an annual Attestation Form, demonstrating compliance with statutory and administrative grant requirements, CPRIT's policies and procedures, grant contract terms, and the Uniform Grant Management Standards. This opportunity to self-report, in the form of a checklist, provides a baseline of grantee compliance and allows compliance specialists to proactively work with grantees towards full compliance prior to a desk review or on-site review. As of April 22, all grantees have submitted their annual Compliance Attestation. Pursuant to Texas Administrative Code §701.19, CPRIT requires Product Development grantees to demonstrate that they will relocate to Texas as a condition of the grant award. As part of the annual attestation process, CPRIT requires Product Development grantees to submit documentation demonstrating compliance with the Texas Location Criteria. Compliance specialists are working with one grantee to submit the required documentation.

Match Expenditures Review

CPRIT requires academic research and product development research grantees to demonstrate that they have available unused funds equal to at least one-half of the CPRIT grant award that the grantee will spend on the CPRIT-funded project. This obligation, often referred to as “CPRIT’s matching funds requirement,” requires the grantee to first certify that it has available matching funds, and then at the end of the grant year, to verify that the grantee spent the matching funds on the project. CPRIT’s statute allows an institution of higher education to use its federal indirect cost rate as a credit toward the required 50% match.

Product development grantees plus those academic research grantees whose indirect cost rate credit does not fully offset the required match must provide a detailed match expenditure report that includes the amount and date paid, vendor, description, and budget category. Compliance staff review grantees’ match expenditures for appropriateness and allowability and work with CPRIT’s grant accountants and the grantee to address any deficiencies. Compliance staff performed two annual match expenditure reviews for two grantees in April. The total amount of match expenses reviewed by compliance staff for FY 2021 is \$12,611,725.12.

Training and Support

CPRIT staff conducted one new grantee training webinar in April for Asyilia Therapeutics. The training covered grant reporting requirements, administrative rule changes, grant closeout, and an overview of the compliance program including fraud, waste, and abuse reporting. Pursuant to Texas Administrative Code §703.22, CPRIT requires new grantees to complete the initial compliance training program prior to receiving disbursement of grant award funds.

Academic Research Program Update

FY 2021 Recruitment Applications

CPRIT’s Scientific Review Council (SRC) met January 20, March 10, and April 15 to review recruitment applications submitted for cycles 21.06 - 21.09. Dr. Willson will present the SRC’s recommendations to the Program Integration Committee (PIC) and the Oversight Committee in May.

FY 21.06 - 21.09 Mechanism	Received	Funds Requested	Proposed by SRC	Funds Proposed by SRC
Recruitment Established Investigators	2	\$12,000,000	1	\$6,000,000
Recruitment of Rising Stars	5	\$18,553,081	2	\$8,000,000
Recruitment of First-Time, Tenure Track Faculty Members	16	\$28,104,769	11	\$22,000,000
TOTAL	23	\$58,657,850	14	\$36,000,000

FY 2021 Review Cycle 1 - Training Applications

CPRIT received 15 applications for research training awards by the October 28, 2020, deadline. Peer reviewers met virtually on February 18 to evaluate the applications and the SRC met on March 26 to approve the award recommendations. Dr. Willson will present the SRC's recommendations to the PIC and the Oversight Committee in May.

RFA Mechanism	Received	Funds Requested	Proposed by SRC	Funds Proposed by SRC
Research Training Awards	15	\$57,385,186	8	\$30,320,920

FY 2021 Review Cycle 2 (21.2)

CPRIT released six academic research RFAs in August 2020 and began accepting applications for the 21.2 review cycle September 16, 2020. In addition to Core Facility Support Awards, High Impact/High Risk Awards, and Early Clinical Investigator Awards, the 21.2 review cycle includes several new RFAs, including the new Clinical Trials Network Award, Texas Clinical Trials Participation Program Award, and Texas Regional Excellence in Cancer Award. Applicants submitted 159 proposals by the January 27 deadline. After peer review in late May, Dr. Willson will present the SRC's recommended research awards to the PIC and the Oversight Committee for consideration in August.

FY 2021 RFA Mechanism	Received	Funds Requested
Core Facility Support Awards	25	\$95,848,572
Clinical Trials Network Awards	5	\$13,481,740
Early Clinical Investigator Awards	11	\$16,426,401
High-Impact/High Risk Awards	107	\$26,501,441
Texas Clinical Trials Participation Program Awards	4	\$5,982,538
Texas Regional Excellence in Cancer Awards	7	\$41,786,641
Total	159	\$200,027,333

FY 2022 Cycle 1 RFAs

CPRIT released the first five RFAs for FY 2022 grant awards on January 13. Applications for the first cycle of FY 2022 (22.1) research awards are due June 2. Peer review panels will convene in October to evaluate the applications and make grant award recommendations. The Chief Scientific Officer will present the SRC's recommendations to PIC and the Oversight Committee in February 2022.

The 22.1 Cycle RFA Mechanisms

- *Individual Investigator Research Awards (IIRA)*
Supports applications for innovative research projects addressing critically important questions that will significantly advance knowledge of the causes, prevention, and/or treatment of cancer. Areas of interest include laboratory research, translational studies, and/or clinical investigations. Competitive renewal applications accepted.
Award: Up to \$350,000 per year. Exceptions permitted if extremely well justified; maximum duration: 3 years.
- *Individual Investigator Research Awards for Computational Systems Biology of Cancer (IIRACSBC)*
Supports applications for innovative mathematical and/or computational research projects addressing questions that will advance current knowledge in the (a) mechanisms that tie altered gene expression and downstream molecular mechanisms to functional cancer phenotypes and/or (b) mechanisms that tie tumor morphology to functional cancer phenotypes and/or mechanisms that tie treatment sequence and combination to evolving functional cancer phenotypes (that emerge as a result of treatment selection).
Award: Up to \$400,000 in total costs per year. Exceptions permitted if extremely well justified; maximum duration: 3 years.
- *Individual Investigator Research Awards for Cancer in Children and Adolescents (IIRACCA)*
Supports applications for innovative research projects addressing questions that will advance knowledge of the causes, prevention, progression, detection, or treatment of cancer in children and adolescents. Laboratory, clinical, or population-based studies are all acceptable. CPRIT expects the outcome of the research to reduce the incidence, morbidity, or mortality from cancer in children and/or adolescents in the near or long term. Competitive renewal applications accepted.
Award: Up to \$350,000 per year. Applicants that plan to conduct a clinical trial as part of the project may request up to \$500,000 in total costs. Exceptions permitted if extremely well justified; maximum duration: 4 years.
- *Individual Investigator Research Awards for Prevention and Early Detection (IIRAP)*
Supports applications which propose clinical and population-based projects designed to develop effective prevention and early detection interventions to reduce cancer risk, mortality, and morbidity among Texans. Projects that propose such research collaborations with existing CPRIT Prevention Program awardees including the CPRIT funded *Texas Collaborative Center for Hepatocellular Cancer* (<https://www.bcm.edu/research/labs-and-centers/research-centers/texas-collaborative-center-for-hepatocellular-cancer>) are strongly encouraged.
Award: Up to \$500,000 per year. Exceptions permitted if extremely well justified; maximum duration: 4 years.

- Individual Investigator Research Awards for Clinical Translation (IIRACT)**
 Supports applications that propose innovative cancer clinical studies that are hypothesis driven and involve patients enrolled prospectively on a clinical trial. Areas of interest include clinical studies of new or repurposed drugs, hormonal therapies, immune therapies, surgery, radiation therapy, stem cell transplantation, combinations of interventions, or therapeutic devices.
 Award: Up to \$500,000 per year. Exceptions permitted if extremely well justified; maximum duration: 4 years.

Product Development Research Program Update

FY 2021 Product Development Research RFAs

CPRIT released three Product Development RFAs on November 9 seeking applications for the Texas Company, Relocation Company, and Seed Company awards. Dr. WalkerPeach and Ms. French hosted a webinar for potential applicants on November 19. CPRIT received 35 eligible applications by the January 27 deadline.

The Product Development peer review panels met by videoconference on March 22 – 23 for initial peer review. Eight companies moved forward to the next part of the review process - live presentations via videoconference, held April 19 – 21. Following the company presentations, the peer review panels recommended five applications for due diligence review. The Product Development Review Council (PDRC) will meet in July to review the due diligence reports and make final recommendations. Dr. WalkerPeach will present the PDRC's award recommendations to the PIC and the Oversight Committee in August.

FY 2021 Grant Mechanism	Received	Funds Requested	Live presentations	Funds Requested	Rec'd for Diligence	Funds Requested
Texas Company	8	\$99,869,430	3	\$41,849,848	3	\$41,849,848
Relocation Company	6	\$97,956,112	2	\$35,568,812	1	\$19,978,500
Seed Company	21	\$55,118,837	3	\$8,988,950	1	\$3,000,000
TOTAL	35	\$252,944,379	8	\$86,407,610	5	\$64,828,348

Prevention Program Update

FY 2021 Cycle 1 (21.1) Prevention Review Cycle

CPRIT released the *Expansion of Cancer Prevention Services to Rural and Medically Underserved Populations* RFA in August 2020 for the first review cycle of FY 2021. CPRIT's prevention peer review panels convened via videoconference on January 19 - 20 to review the 12 applications requesting \$26,133,587 in grant funds. The Prevention Review Council (PRC) met

March 4 to consider the applications. Ms. Magid will present the PRC's five grant award recommendations totaling \$11.2 million to the PIC and the Oversight Committee in May.
FY 2021 Cycle 2 (21.2) Prevention RFAs

CPRIT released four 21.2 RFAs (listed below) in October 2020. CPRIT received 22 applications requesting \$24.5 million by the February 10 deadline. Peer reviewers convened April 26-29 to evaluate the applications. Ms. Magid will present the PRC's 21.2 recommendations to the PIC and the Oversight Committee in August.

21.2 Grant Mechanism	Received	Funds Requested
Dissemination of CPRIT-Funded Cancer Control Interventions	4	\$ 1,198,638
Evidence-based Cancer Prevention Services	10	\$ 9,724,716
Expansion of Cancer Prevention Services to Rural and Medically Underserved Populations	3	\$ 6,580,487
Tobacco Control and Lung Cancer Screening	5	\$ 6,973,002
TOTAL	22	\$24,476,843

FY 2021 Prevention Program RFAs

- Dissemination of CPRIT-Funded Cancer Control Interventions*
 Seeks to fund projects that will facilitate the dissemination and implementation of successful CPRIT-funded, evidence-based cancer prevention and control interventions across Texas. The proposed project should be able to develop one or more "products" based on the results of the CPRIT-funded intervention. The proposed project should also identify and assist others to prepare to implement the intervention and/or prepare for grant funding.
 Award: Maximum of \$300,000 over 24 months.
- Evidence-Based Cancer Prevention Services*
 Seeks projects that will deliver evidence-based cancer prevention and control clinical services. CPRIT will give priority to projects that propose to address CPRIT areas of emphasis and serve areas of the state not well addressed by current CPRIT funded projects.
 Award: Up to \$1 million over 36 months.
- Tobacco Control and Lung Cancer Screening*
 Seeks programs on tobacco prevention and cessation, as well as screening for early detection of lung cancer. Through release of this RFA, CPRIT's goal is to stimulate more programs across the state, thereby providing greater access for underserved populations and reducing the incidence and mortality rates of tobacco-related cancers. This RFA seeks to promote and deliver evidence-based programming designed to significantly increase tobacco cessation among adults and/or prevent tobacco use by youth.
 New Award: Up to \$1 million over 36 months.
 Expansion Award: Up to \$2.5 million over 3 years.

- *Expansion of Cancer Prevention Services to Rural and Medically Underserved Populations*
Seeks to support coordination and expansion of evidence-based services to prevent cancer in underserved populations who do not have adequate access to cancer prevention interventions and health care, bringing together networks of public health and community partners to carry out programs tailored for their communities. Projects should identify cancers that cause the most burden in the community and use evidence-based models shown to work in similar communities to prevent and control these cancers. Currently funded CPRIT projects should propose to expand their programs to include additional types of prevention clinical services and/or an expansion of current clinical services into additional counties. In either case, the expansion must include delivery of services to nonmetropolitan and medically underserved counties in the state.
Initial Expansion Award: Up to \$2 million over 3 years.
Subsequent Expansion Award: Up to \$2.5 million over 5 years.

Advisory Committee Meetings

Presiding Officer Dee Margo directed me to create a Geographical Diversity University Advisory Committee. I contacted leadership at the following institutions for candidates for membership: Texas A&M University, Texas Tech University Health Sciences Center, Texas Tech University Health Sciences Center El Paso, Baylor University, The University of Texas at Tyler, The University of Texas Rio Grande Valley, and The University of Texas at El Paso. The Oversight Committee will vote to approve the inaugural members at the May 19 meeting.

Several CPRIT advisory committees met in April to prepare for annual presentations to the Oversight Committee on May 19. All meetings are via videoconference.

- The Product Development Advisory Committee met April 14
- The Advisory Committee on Childhood Cancers met April 26
- The University Advisory Committee met April 30

Operations, Audit and Finance Update

State Auditor's Office Audit

The State Auditor's Office (SAO) audit team continues field work on the grant management audit. They updated the period of audit coverage after they determined that the initial grant award period overlapped with the pre-award grant management audits performed by Weaver and Tidwell in 2017 and 2018.

Services Contracts

- CPRIT issued a competitive request for proposals (RFP) for grant management support services on February 25 after addressing some procurement requirements raised during the mandated review by the Contract Advisory Team (CAT). CAT is a statewide procurement review committee that assesses RFP documents for risk mitigation when the expected

contract will exceed \$5 million. Chief Operating Office Heidi McConnell will present the staff recommendation for a grant management support services contract for approval at the May 19 Oversight Committee meeting. The contract is necessary to continue grant management support services for fiscal year 2022 and beyond.

- On February 8 CPRIT issued an RFP for financial audit services. CPRIT received five proposals by the March 8 due date. The financial audit services contract does not require Oversight Committee approval because it is less than \$100,000; Ms. McConnell will notify you of staff's decision regarding the contract at the May meeting.

Communications Update

Media Highlights

KPRC Houston produced a segment about the projected reduction of fatal cancers over the next 20 years and referenced CPRIT in its reporting. CPRIT Scholars Kevin Nead, M.D., and Mackenzie Wehner, M.D., at The University of Texas MD Anderson Cancer Center co-authored the study.

04/9/21 - Deaths from the 2 most fatal cancers in the US could be reduced within the next 20 years - KPRC Houston: <https://app.criticalmention.com/app/#/clip/public/8516bd8d-e4ee-4981-9abe-d23ee790d950>

Media Relations

Long-time *Houston Chronicle* health care reporter Todd Ackerman has retired and is now a writer at Houston Methodist. Mr. Ackerman covered CPRIT extensively. His retirement means that there are no more health care specialist journalists at any of the major Texas newspapers.

Social Media

April is National Minority Cancer Awareness Month, and CPRIT focused our social media posts on several grantees and projects in this area, including the work of CPRIT Scholar Dr. Christopher Flowers, the Liver Cancer CAP, and a Baylor College of Medicine screening program that serves Asian Americans and other underserved communities.

CPRIT also produced a video featuring cancer survivor Janice Robbins. She spoke about how their CPRIT-funded programs at the Moncrief Cancer Institute saved her life. We have posted the video on CPRIT's social media channels. https://www.youtube.com/watch?v=b98fe0_4xnQ

National Oral, Head, and Neck Cancer Awareness Week was April 12-16. CPRIT's stakeholders and advocates retweeted and liked CPRIT's social media posts highlighting our grantees' work addressing these cancers. CPRIT posts featured OncoNano, Dr. Jane Montealegre of Baylor College of Medicine, and Perimeter's FDA device approval.

Social Media Statistics

- Twitter (March 26 – April 22)

Total Tweets: 12

Tweet Impressions: 25,300

Profile Visits: 798

Mentions: 13

New Followers: 27 (2,826 total)

Top tweet: Tobacco & HPV are known causes of oral, head & neck cancers. Dr. Jane Montealegre of @bcmhouston leads efforts against both in @harrishealth clinics by improving HPV vaccine completion rates in underserved youth and screening them for tobacco use: <https://cpvit.us/3df9jJt> #OHANCAW

Impressions: 5,229

Engagements: 104

- LinkedIn (March 22 – April 21)

Total Updates: 16

Post Impressions: 3,200

Reactions: 58

Shares: 3

Page views: 119

Unique Visitors: 57

New followers: 19 (1,172 total)

Top Update: CPRIT has awarded OncoNano Medicine, Inc. \$16 million to develop nanotechnology-enabled real time imaging that assists cancer surgeons excise solid tumors. Known as ONM-100, the technology is in Phase II clinical trials for various cancer sites, including #colorectalcancer. <https://cpvit.us/3dh5NNh> #CRCawareness

Impressions: 424

Clicks: 28

Reactions: 12

Engagement rate: 9.67 %

- Facebook (March 25 – April 21)

Reach: 1,297 people

Engagement: 570 reactions/clicks

Page Views: 123

Top Post: Tobacco and HPV are known causes of oral, head and neck cancers. Dr. Jane Montealegre of Baylor College of Medicine is leading efforts against both. In eight Harris Health System, her efforts have led to an 80% HPV vaccine series completion rate among

underserved youth - up from 46%. At the clinics, patients are screened for e-cigarette use and tobacco prevention materials are distributed as they wait following vaccinations. Read more about her program: [#OHANCAW](https://cpvit.us/3df9jJt)

Post Reach: 723 people

Engagement: 179 clicks, 261 reactions, 4 shares

Upcoming Subcommittee Meetings

The Special Issues Subcommittee met April 20 and April 28 to discuss legislative issues. Listed below are the subcommittee meetings in advance of the May 19 Oversight Committee meeting.

Board Governance	May 6 at 10:00 a.m.
Audit	May 10 at 10:00 a.m.
Prevention	May 11 at 10:00 a.m.
Academic Research	May 12 at 10:00 a.m.
Product Development	May 13 at 10:00 a.m.
Nominations	May 14 at 10:30 a.m.

We will send instructions for signing onto the Zoom platform along with the subcommittee agenda and meeting materials one week prior to the meeting date. Please plan to join the subcommittee meeting a few minutes early so we can address any technology issues before the meeting start time.

CPRIT has awarded **1,585** grants totaling **\$2.669 billion**

- 244 prevention awards totaling \$277.7 million
- 1,341 academic research and product development research awards totaling \$2.392 billion

Of the \$2.392 billion in academic research and product development research awards,

- 30.5% of the funding (\$730.0 million) supports clinical research projects
- 24.4% of the funding (\$582.0 million) supports translational research projects
- 28.9% of funding (\$691.6 million) supports recruitment awards
- 13.7% of the funding (\$327.7 million) supports discovery stage research projects
- 2.5% of funding (\$60.0 million) supports training programs.

CPRIT has 8 open Requests for Applications (RFAs)

- 3 Research Recruitment
- 5 Academic Research



CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

MEMORANDUM

TO: OVERSIGHT COMMITTEE MEMBERS
FROM: VINCE BURGESS, CHIEF COMPLIANCE OFFICER
SUBJECT: COMPLIANCE PROGRAM UPDATE
DATE: MAY 10, 2021

The Chief Compliance Officer is responsible for apprising the Oversight Committee and the Chief Executive Officer of institutional compliance functions and activities, and assuring the Oversight Committee that controls are in place to prevent, detect and mitigate compliance risk. The required reporting includes quarterly updates to the Oversight Committee on CPRIT's compliance with applicable laws, rules, and agency policies. In addition, the Compliance Officer is responsible for monitoring the timely submission status of required grant recipient reports and notifying the Oversight Committee and General Counsel of a grant recipient's failure to meaningfully comply with reporting deadlines.

Submission Status of Required Grant Recipient Reports

CPRIT has \$1.4 billion in active grants under management, with 560+ grants that are either active or wrapping up grant activities. We receive an average of 560 grantee reports each month. As of April 26, four entities had not filed one Academic Research report and five Product Development Research reports. CPRIT's grant accountants and compliance specialists review and process incoming reports and reach out to grantees to resolve filing issues. In most cases, CPRIT does not disburse grant funds until the grantee files the required reports. In some instances, grantee institutions may be ineligible to receive a future award if the grantee does not submit the required reports.

Financial Status Report Reviews

CPRIT's compliance specialists performed 582 second-level reviews of grantee Financial Status Reports (FSRs) in February, March, and April. Sixty-one FSRs (10%) required resubmission due to insufficient or inaccurate documentation submitted by the grantee. CPRIT's grant accounting staff completes the initial review of the FSRs and supporting documentation before routing them to the compliance specialists for final review and disposition.

Single Audit Tracking

Compliance specialists track the submission of grantees' independent audit reports and the resolution of issues identified in these reports. Grantees who expend \$750,000 or more in state awards in the grantee's fiscal year must submit a single independent audit, a program specific

audit, or an agreed upon procedures engagement. The grantee submits the independent audit report with findings to CPRIT within 30 days of receipt, but no later than nine months after the grantee's fiscal year end.

Currently, all grantees have submitted the required audits. Grantees are unable to receive reimbursements or advances if they are delinquent in filing the required audit and corrective action plan unless the grantee requested additional time by the due date of the required audit and CPRIT's CEO approved the request.

Desk Reviews

Compliance specialists performed eight enhanced desk-based financial monitoring reviews in February, March, and April. Enhanced desk reviews verify that grantees expend funds in compliance with specific grant requirements and guidelines and may target an organization's internal controls, current and past fiscal audits, and timeliness of required grantee report submission. Compliance specialists are working with one grantee to remediate enhanced desk review findings.

Onsite Reviews

CPRIT completed 12 virtual onsite reviews in February, March, and April. Onsite reviews examine the grantee's financial and administrative operations, subcontract monitoring, procurement and contracting procedures, inventory procedures, personnel policies and procedures, payroll and timesheet policies, travel policies and records, and single audit compliance. Compliance specialists are working with one grantee to remediate onsite review findings.

Annual Compliance Attestation

CPRIT requires grantees to submit an annual Compliance Attestation form to verify compliance with statutory and administrative grant requirements, CPRIT's policies and procedures, grant contract terms, and the Uniform Grant Management Standards. This opportunity to self-report, in the form of a checklist, provides a baseline of grantee compliance and allows compliance specialists to proactively work with grantees towards full compliance prior to a desk review or onsite review. All grantees have submitted their annual Compliance Attestation for this calendar year. As part of the annual attestation process, CPRIT requires Product Development grantees to submit documentation demonstrating compliance with the Texas Location Criteria pursuant to Texas Administrative Code §701.19. Compliance specialists are working with one grantee to submit the required documentation.

Match Expenditures Review

CPRIT requires academic research and product development research grantees to demonstrate that they have available unused funds equal to at least one-half of the CPRIT grant award that the grantee will spend on the CPRIT-funded project. This obligation, often referred to as "CPRIT's

matching funds requirement,” requires the grantee to first certify that it has available matching funds, and then at the end of the grant year, to verify that the grantee spent the matching funds on the project. CPRIT’s statute allows an institution of higher education to use its federal indirect cost rate (FICR) as a credit toward the required 50% match.

Product development grantees plus those academic research grantees whose indirect cost rate credit does not fully offset the required match must provide a detailed match expenditure report that includes the amount and date paid, vendor, description, and budget category. Compliance staff reviews grantee match expenditures for appropriateness and allowability and work with CPRIT’s grant accountants and the grantee to address any deficiencies. Compliance staff performed two annual match expenditure reviews for two grantees in April. The total amount of match expenses reviewed to date by compliance staff for FY21 is \$12,611,725.12. Of the total amount reviewed, \$836,561.92 (6.6%) has been identified as unallowable.

Training and Support

CPRIT staff conducted two new grantee training webinars this quarter: Immunogenesis, Inc. and Asyilia Therapeutics. The trainings covered grant reporting requirements, administrative rule changes, grant closeout, and an overview of the compliance program including fraud, waste, and abuse reporting. Pursuant to Texas Administrative Code §703.22, CPRIT requires new grantees to complete the initial compliance training program prior to receiving disbursement of grant award funds.

Annual Compliance Training webinars were conducted on March 9-11 with approximately 200 grantee staff in attendance. Trainings are specific to each program area (Academic Research, Product Development Research, and Prevention) and allow for an interactive experience and opportunity to focus on topics relevant to each program. The trainings cover grant reporting requirements, administrative rule changes, grant closeout, and an overview of the compliance program including fraud, waste, and abuse reporting. A second series of Compliance Training webinars have been scheduled for June 9-10. CPRIT requires the Authorized Signing Official (ASO) and at least one other employee from each grantee organization to attend an annual compliance training by December 31 of each year.



CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

MEMORANDUM

TO: OVERSIGHT COMMITTEE MEMBERS
FROM: JAMES WILLSON, M.D., CHIEF SCIENTIFIC OFFICER
SUBJECT: ACADEMIC RESEARCH PROGRAM FY2022.1 PROPOSED SCHOLAR RFAS AND OPEN RFAS.
DATE: MAY 19, 2021

Proposed Academic Research Scholar RFAs for Fiscal Year 2022 Cycle 1 (22.1)

The Academic Research Program proposes the following Scholar RFAs for FY22.1:

- **Recruitment of Established Investigators (RFA R-22-1 REI):**
Recruits outstanding senior research faculty with distinguished professional careers and established cancer research programs to academic institutions in Texas.
Award: Up to \$6 million over a period of five years.
- **Recruitment of Rising Stars (RFA R-22-1 RRS):**
Recruits outstanding early-stage investigators to Texas, who have demonstrated the promise for continued and enhanced contributions to the field of cancer research.
Award: Up to \$4 million over a period of five years.
- **Recruitment of First-Time Tenure -Track Faculty Members (RFA R-22-1. RFT):**
Supports very promising emerging investigators, pursuing their first faculty appointment in Texas, who have the ability to make outstanding contributions to the field of cancer research.
Award: Up to \$2 million over a period up to five years.

FY2021 Cycle 2 (21.2)

Table 2 displays an overview of applications submitted by mechanism on January 27, 2021 for FY2021 Cycle 2 RFAs. Dr. Willson will present the Scientific Review Council's recommendations to PIC and the Oversight Committee in August 2021.

Table 2: FY2021 Cycle 2 (21.2) Submission Data

RFA Mechanism	# Applications Submitted	Requested Funding
Core Facility Support Awards	25	\$95,848,572
Clinical Trials Network Awards	5	\$13,481,740
Early Clinical Investigator Award	11	\$16,426,401
High-Impact/High Risk Awards	107	\$26,501,441
Texas Clinical Trials Participation Program Award	4	\$5,982,538
Texas Regional Excellence in Cancer Award	7	\$41,786,641
Total	159	\$200,027,333

FY 2022 Cycle 1 (22.1) Academic Research RFAs

CPRIT released four (5) RFAs on March 3, 2021 for the first cycle of FY2022. Applications are due on June 2, 2021 and a virtual peer review is scheduled for October 2021. Dr. Willson will present the Program Integration Committee's recommendations to the Oversight Committee in February 2022.

FY22.1 RFA Mechanisms

- **Individual Investigator Research Awards (IIRA)**
Supports applications for innovative research projects addressing critically important questions that will significantly advance knowledge of the causes, prevention, and/or treatment of cancer. Areas of interest include laboratory research, translational studies, and/or clinical investigations. Competitive renewal applications accepted.
Award: Up to \$350,000 per year. Exceptions permitted if extremely well justified; maximum duration: 3 years.
- **Individual Investigator Research Awards for Computational Systems Biology of Cancer (IIRACSB)**
Supports applications for innovative mathematical and/or computational research projects addressing questions that will advance current knowledge in the (a) mechanisms that tie altered gene expression and downstream molecular mechanisms to functional cancer phenotypes and/or (b) mechanisms that tie tumor morphology to functional cancer phenotypes and/or mechanisms that tie treatment sequence and combination to evolving functional cancer phenotypes (that emerge as a result of treatment selection).
Award: Up to \$400,000 in total costs per year for up to 4 years. Exceptions permitted if extremely well justified.

- **Individual Investigator Research Awards for Cancer in Children and Adolescents (IIRACCA)**

Supports applications for innovative research projects addressing questions that will advance knowledge of the causes, prevention, progression, detection, or treatment of cancer in children and adolescents. Laboratory, clinical, or population-based studies are all acceptable. CPRIT expects the outcome of the research to reduce the incidence, morbidity, or mortality from cancer in children and/or adolescents in the near or long term. Competitive renewal applications accepted.

Award: Up to \$350,000 per year. Applicants that plan on conducting a clinical trial as part of the project may request up to \$500,000 in total costs. Exceptions permitted if extremely well justified; maximum duration: 4 years.

- **Individual Investigator Research Awards for Prevention and Early Detection (IIRAP)**

Supports applications which propose clinical and population-based projects designed to develop effective prevention and early detection interventions to reduce cancer risk, mortality, and morbidity among Texans. Projects that propose such research collaborations with existing CPRIT Prevention Program awardees including the CPRIT funded *Texas Collaborative Center for Hepatocellular Cancer*

(<https://www.bcm.edu/research/labs-and-centers/research-centers/texas-collaborative-center-for-hepatocellular-cancer>) are strongly encouraged.

Award: Up to \$500,000 per year. Exceptions permitted if extremely well justified; maximum duration: 4 years.

- **Individual Investigator Research Awards for Clinical Translation (IIRACT)**

Supports applications that propose innovative cancer clinical studies that are hypothesis driven and involve patients enrolled prospectively on a clinical trial. Areas of interest include clinical studies of new or repurposed drugs, hormonal therapies, immune therapies, surgery, radiation therapy, stem cell transplantation, combinations of interventions, or therapeutic devices.

Award: Up to \$500,000 per year. Maximum duration: 4 years. Exceptions permitted if extremely well justified.



CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

MEMORANDUM

TO: OVERSIGHT COMMITTEE MEMBERS
FROM: RAMONA MAGID, CHIEF PREVENTION OFFICER
SUBJECT: PREVENTION PROGRAM UPDATE
DATE: MAY 19, 2021

FY 2021 Cycle 2 (21.2) Prevention Applications

CPRIT released four (4) RFAs on October 15, 2020 for the second cycle of FY 2021. The application deadline was February 10, 2021. The eighteen (18) applications requesting \$23,278,205 underwent peer review on April 26. The Prevention Review Council (PRC) will meet on June 17 to review the four (4) Dissemination applications requesting \$1,198,638 and the results of the peer review panel. Ms. Magid will present the PRC's recommendations to the Program Integration Committee (PIC) and the Oversight Committee (OC) in August 2021.

FY 2021.2 (21.2) Application Data by Mechanism

Mechanism	Received	Funds Requested
Dissemination of CPRIT-Funded Cancer Control Interventions	4	\$ 1,198,638
Evidence-based Cancer Prevention Services	10	\$ 9,724,716
Expansion of Cancer Prevention Services to Rural and Medically Underserved Populations	3	\$ 6,580,487
Tobacco Control and Lung Cancer Screening	5	\$ 6,973,002
TOTAL	22	\$24,476,843

FY 2022 Cycle 2 (22.1) Prevention RFAs

CPRIT released four (4) RFAs on May 7 for the first cycle of FY2022. Applications are due on September 1, 2021 and peer review is scheduled for December 2021. Ms. Magid will present the PIC's recommendations to the OC in February 2022.

Dissemination of CPRIT-Funded Cancer Control Interventions

This award mechanism seeks to fund projects that will facilitate the dissemination and implementation of successful CPRIT-funded, evidence-based cancer prevention and control interventions across Texas. The proposed project should be able to develop one or more "products" based on the results of the CPRIT-funded intervention. The proposed project should also identify and assist others to prepare to implement the intervention and/or prepare for grant funding.

Award: Maximum of \$300,000; Maximum duration of 24 months.

Evidence-Based Cancer Prevention Services

Evidence-Based Cancer Prevention Services - This award mechanism seeks to fund projects that will deliver evidence-based cancer prevention and control clinical services. Priority will be given to projects that propose to address CPRIT areas of emphasis and serve areas of the state not well addressed by current CPRIT funded projects.

Award: Maximum of \$1M; Maximum duration of 36 months.

Expansion of Cancer Prevention Services to Rural and Medically Underserved Populations

This award mechanism seeks to support the coordination and expansion of evidence-based services to prevent cancer in underserved populations who do not have adequate access to cancer prevention interventions and health care, bringing together networks of public health and community partners to carry out programs tailored for their communities. Projects should identify cancers that cause the most burden in the community and use evidence-based models shown to work in similar communities to prevent and control these cancers. Currently funded CPRIT projects should propose to expand their programs to include additional types of prevention clinical services and/or an expansion of current clinical services into additional counties. For projects requesting a maintenance expansion, expansion of clinical services or geographic area is optional; however, the number of clinical services delivered should be substantially increased.

Initial Expansion Award: Maximum of \$2M; Maximum duration of 36 months.

Maintenance Expansion Award: Maximum of \$2.5M; Maximum duration of 60 months.

Tobacco Control and Lung Cancer Screening

This award mechanism seeks to fund programs on tobacco prevention and cessation, as well as screening for early detection of lung cancer. Through release of this RFA, CPRIT's goal is to stimulate more programs across the state, thereby providing greater access for underserved populations and reducing the incidence and mortality rates of tobacco-related cancers. This RFA

seeks to promote and deliver evidence-based programming designed to significantly increase tobacco cessation among adults and/or prevent tobacco use by youth.

Award: Maximum of \$1M for new projects and \$2M for expansion projects; Maximum duration of 36 months.

Prevention Program Assessment

This award mechanism solicits applications for one project to assess the initial progress of the CPRIT Prevention Program since 2010 and to develop an assessment plan for the next stage of the CPRIT Prevention Program. The evaluation will use a mixed-methods approach, which combines quantitative and qualitative data to provide evidence of effectiveness and information about how CPRIT-related changes are embedded and sustained in organizations and populations. Evaluation findings will be used to improve program effectiveness and to inform decisions about future program development.

Award: Maximum of \$750,000; Maximum duration of 24 months.

Other Activities

Ms. Magid attended several national meetings, all held virtually: Annual American Association for Cancer Research (AACR) on April 10-15 and May 17-21; Prevent Cancer Dialogue on April 7, May 5, and June 2; and the National Colorectal Cancer Roundtable's 2021 Colorectal Cancer Awareness Month webcast in April.

Ms. Magid presented an update on CPRIT activities at the Cancer Alliance of Texas meeting on May 13.

Ms. Magid was invited to participate in the "Addressing Colorectal Cancer Screening: What Can Payers and Employers Do to Improve Screening Rates in Texas" symposium, hosted by a collaboration with the National Association of Chronic Disease Directors (NACDD), the Centers for Disease Control and Prevention, and Texas Department of State Health Services initiative to increase Colorectal Cancer Screening.



CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

MEMORANDUM

TO: OVERSIGHT COMMITTEE MEMBERS
FROM: CINDY WALKERPEACH, PHD
CHIEF PRODUCT DEVELOPMENT OFFICER
SUBJECT: PRODUCT DEVELOPMENT RESEARCH UPDATE
DATE: 07MAY2021

Product Development Research Award Update

Product Development Research FY 2021 Cycle 1

CPRIT released the TXCO, RELCO and SEED Product Development Research RFAs on November 9, 2020, and accepted applications through January 27, 2021. Applicants submitted thirty-six (36) responses to the RFAs. Upon administrative review, one (1) application was withdrawn, resulting in a total of thirty-five (35) applications moving forward for review. See Table 1. The peer review screen held on March 22-23, 2021, resulted in a total of eight (8) applications invited to in-person presentations (via Zoom) from April 19-22, 2021. As a result of the Peer Review Meeting, the peer review panels recommended five (5) applications to move forward to the diligence evaluation phase of review. Dr. WalkerPeach, Chief Product Development Officer, anticipates presenting the peer review recommendations for FY2021 Cycle 1 to the Oversight Committee during the August 2021 Oversight Committee meeting.

Table 1: Product Development Research FY2021 Cycle 1 Application Data by Mechanism

Mechanism	Applications Received	Funds Requested (millions)	Invited to Peer Review Meeting	Funds Requested (millions)	Rec'd for Diligence Review	Funds Requested (millions)
Texas Company	8	\$99,869,430	3	\$41,849,848	3	\$41,849,848
Relocation Company	6	\$97,956,112	2	\$35,568,812	1	\$19,978,500
Seed Company	21	\$55,118,837	3	\$8,988,950	1	\$3,000,000
TOTAL	35	\$252,944,379	8	\$86,407,610	5	\$64,828,348

Product Development Research FY 2022 Cycle 1 and 2

Dr. WalkerPeach presented, and the Oversight Committee approved, the following three (3) RFAs during the February OC meeting:

- *Texas Company Product Development Research Award (TXCO):*
RFA supporting TX based company product development research projects
Award: Up to \$20 million over a maximum timeline of three years.
- *Company Relocation Product Development Award (RELCO):*
RFA supporting product development research projects for companies relocating to TX
Award: Up to \$20 million over a maximum timeline of three years.
- *Seed Award for Product Development Research (SEED):*
RFA supporting product development research projects from newly formed companies
Award: Up to \$3 million over a maximum timeline of three years.

Product Development Research anticipates opening the application portal for Cycle 22.1 in June 2021, with an anticipated presentation of award recommendations at the February 2022 OC Meeting. For the 22.2 Cycle, Product Development Research anticipates opening the application portal in November/December 2021, with an anticipated presentation of award recommendations at the August 2022 OC Meeting.

**May 2021 Oversight Committee
Internal Audit Status Report
As of May 3, 2021**

Weaver and Tidwell, LLP (Weaver) is the outsourced internal auditor of the Cancer Prevention Research Institute of Texas (CPRIT). The Weaver engagement team is led by Daniel Graves, Partner and Alyssa Martin, Partner.

2021 Internal Audit Plan and Schedule

Based on the approved 2021 Internal Audit Plan by the Oversight Committee, we have coordinated and planned the timing of the internal audits and follow-up procedures for the 2021 Internal Audit Plan.

2021 INTERNAL AUDITS		
Internal Audit	Description	Status
Sunset Self-Assessment Advisory Audit	<p>The advisory audit was planned to provide CPRIT a risk-based framework and an overlay of internal audits and controls in preparation for the Self-Assessment Report for the Sunset Commission Review. The advisory audit has been cancelled because there is a bill, SB 73, moving quickly through the legislature that changes CPRIT's sunset date from 2023 to 2029.</p> <p>Planning for the advisory audit, and the creation of the framework and mapping of audits to the Self-Assessment Report criteria were complete when SB 713 was voted out of the Senate Committee on Administration on April 14, 2021. It passed the Senate on April 19, and was voted out of the house State Affairs Committee on April 29</p>	Cancelled
Information Technology General Computer Controls	<p>The Internal Audit to evaluate the risks and internal controls in place related to CPRIT's Information Technology practices is underway.</p> <p>Initial planning meetings for the evaluation of Network Operations, Help Desk Support, Change Management, Website Maintenance, Back-Up and Recovery have been completed.</p> <p>The procedures to complete the internal audit are in-progress.</p>	In-Progress
Records Management – Grantee Compliance Records Advisory Audit	<p>Internal Audit will provide audit advisory services to evaluate the planning process for the grantee compliance record migration from a third-party designed system to the integrated CPRIT system. Evaluation of the designed process will include the validation of the system architecture design and data mapping of the file migration plan. Consulting services will also include the validation of the system configuration upon implementation, verification of the completeness of the data migration and testing the accuracy of data classification and mapping.</p>	May 2021

2021 INTERNAL AUDIT FOLLOW-UPS		
Information Security Follow-Up • 2 findings	Internal Audit will perform follow-up procedures on the open findings from the 2016 Internal Audit to ensure corrective action has been taken.	In-Progress with the IT Controls Audit
Communications Follow-Up • 1 High Finding • 2 Moderate Findings	Internal Audit will perform follow-up procedures on the 3 open findings from the 2018 Internal Audit to ensure corrective action has been taken.	In-Progress with the IT Controls Audit
Governance Follow-up • 1 Moderate Finding	Internal Audit will perform follow-up procedures on the open finding from the 2020 Internal Audit to ensure corrective action has been taken.	May 2021
Disaster Recovery and Business Continuity Planning Advisory Follow-up	Internal Audit will perform follow-up procedures on the recommendations provided from the 2020 Advisory project to evaluate the corrective action and provide additional recommendations.	June 2021

We have prepared a summary schedule of audits, their status and a summary of the findings by risk rating. The schedule maps out the internal audit and follow-up procedures performed, by year, the report date, report rating, and the findings by risk rating. The summary schedule is attached.



Daniel Graves, CPA, Internal Auditor
Partner
Weaver and Tidwell L.L.P.



Alyssa G. Martin, CPA, MBA, Internal Auditor
Partner
Weaver and Tidwell L.L.P.

Cancer Prevention and Research Institute of Texas
Schedule of Audits, Status, and Findings Summary
As of May 3, 2021

					Open Findings				Closed Findings				Total Findings			
Audit	Fiscal Year	Status/Timing	Report Date	Report Rating	High	Mod	Low	Total	High	Mod	Low	Total	High	Mod	Low	Total
Fiscal Year 2017																
Training Program Internal Audit	2017	Complete	March 10, 2017	Strong	-	2	-	2	-	-	-	-	-	2	-	2
Internal Agency Compliance	2017	Complete	April 17, 2017	Strong	-	1	-	1	-	-	-	-	-	1	-	1
Pre-Award Grant Management	2017	Complete	May 30, 2017	Satisfactory	1	2	-	3	-	-	-	-	1	2	-	3
Procurement and P-Card Internal Audit	2017	Complete	August 4, 2017	Satisfactory	-	7	2	9	-	-	-	-	-	7	2	9
2016 Information Security Follow-Up	2017	Complete	May 30, 2017													
2016 Commodity and Service Contracts Follow-Up	2017	Complete	July 13, 2017	Strong	-	3	2	5	-	3	2	5	-	-	-	-
2016 Revenue Follow-Up	2017	Complete	July 8, 2017	Strong	-	-	2	2	-	-	2	2	-	-	-	-
2016 Cash Management Follow-Up	2017	Complete	July 13, 2017	Strong	-	1	-	1	-	1	-	1	-	-	-	-
Fiscal Year 2017 Subtotal					1	16	6	23	-	4	4	8	1	12	2	15
Fiscal Year 2018																
Post Award Grant Monitoring Internal Audit	2018	Complete	February 1, 2018	Strong	-	1	-	1	-	-	-	-	-	1	-	1
Grant Contracting Internal Audit																
Communications Internal Audit	2018	Complete	April 30, 2018	Satisfactory	1	4	-	5	-	-	-	-	1	4	-	5
2016 Information Security Follow-Up	2018	Complete	July 17, 2018													
2017 Training Program Follow-Up	2018	Complete	January 19, 2018	Strong	-	2	-	2	-	2	-	2	-	-	-	-
2017 Internal Agency Compliance Follow-Up	2018	Complete	January 19, 2018	Strong	-	1	-	1	-	1	-	1	-	-	-	-
2017 Pre-Award Grant Management Follow-Up	2018	Complete	April 24, 2018	Strong	1	2	-	3	1	2	-	3	-	-	-	-
2017 Procurement and P-Card Follow-Up	2018	Complete	April 30, 2018	Strong	-	7	2	9	-	6	2	8	-	1	-	1
Fiscal Year 2018 Subtotal					2	17	2	21	1	11	2	14	1	6	-	7
Fiscal Year 2019																
State Reporting Internal Audit	2019	Complete	January 16, 2019	Strong	-	-	2	2	-	-	2	2	-	-	-	-
Budget and Planning	2019	Complete	January 16, 2019	Strong	-	-	-	-	-	-	-	-	-	-	-	-
2017 SAO Performance Measures Follow-up	2019	Complete	December 6, 2018	Strong	-	-	3	3	-	-	3	3	-	-	-	-
2016 Information Security Follow-Up	2019	Cancelled	N/A													
2018 Communications Follow-Up	2019	Complete	August 30, 2019	Satisfactory	1	4	-	5	-	2	-	2	1	2	-	3
2018 Post Award Grant Monitoring Follow-Up																
2018 Grant Contracting Follow-Up	2019	Complete	April 11, 2019	Strong	-	1	-	1	-	1	-	1	-	-	-	-
2017 Procurement and P-Card Follow-Up	2019	Complete	August 1, 2019	Strong	-	7	2	9	-	7	2	9	-	-	-	-
Fiscal Year 2019 Subtotal					1	12	7	20	-	10	7	17	1	2	-	3
Fiscal Year 2020																
Governance	2020	Complete	October 30, 2020	Strong	-	1	-	1	-	-	-	-	-	1	-	1
Disaster Recovery and Business Continuity Planning	2020	Complete	October 28, 2020	N/A	-	-	-	-	-	-	-	-	-	-	-	-
2016 Information Security Follow-Up	2020	August 2020	N/A													
2018 Communications Follow-Up	2020	November 2020	N/A	N/A	1	4	-	5	-	2	-	2	1	2	-	3
2019 State Reporting Follow-Up	2020	July 2020	July 20, 2020	Strong	-	-	2	2	-	-	2	2	-	-	-	-
Fiscal Year 2020 Subtotal					1	5	2	8	-	2	2	4	1	3	-	4
Fiscal Year 2021																
Sunset Self-Assessment Advisory	2021	Cancelled	N/A	N/A	-	-	-	-	-	-	-	-	-	-	-	-
Information Technology General Computer Controls	2021	In Progress	October 28, 2020	N/A	-	-	-	-	-	-	-	-	-	-	-	-
Grantee Compliance Records Management	2021	May 2021	N/A	N/A												
2016 Information Security Follow-Up	2021	May 2021	N/A													
2018 Communications Follow-Up	2021	May 2021	N/A	N/A	1	4	-	5	-	2	-	2	1	2	-	3
2020 Governance Follow-up	2021	May 2021	October 2020	Strong	-	1	-	1	-	-	-	-	-	-	-	1
2020 Disaster Recovery and Business Continuity Follow-up	2021	June 2021	October 2020	N/A	-	-	-	-	-	-	-	-	-	-	-	-
Fiscal Year 2021 Subtotal					1	5	-	6	-	2	-	2	1	2	-	4
Open Items Summary																
Audit	Fiscal Year	Status/Timing	Report Date	Report Rating	Findings				Closed Findings				Total Open Findings			
					High	Mod	Low	Total	High	Mod	Low	Total	High	Mod	Low	Total
Governance	2020	July 2020	October 30, 2020	Strong	-	1	-	1	-	-	-	-	-	1	-	1
2016 Information Security Follow-Up	2020	August 2020	N/A													
2018 Communications Follow-Up	2020	November 2020	N/A	N/A	1	4	-	5	-	2	-	2	1	2	-	3
Total Findings For Internal Audit Follow-Up					1	5	-	6	-	2	-	2	1	3	-	4



CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

MEMORANDUM

TO: OVERSIGHT COMMITTEE MEMBERS
FROM: CAMERON ECKEL, ASSISTANT GENERAL COUNSEL
SUBJECT: APPOINTMENTS TO THE SCIENTIFIC RESEARCH AND
PREVENTION PROGRAMS COMMITTEE
DATE: MAY 10, 2021

Summary and Recommendation

The Chief Executive Officer has appointed three experts to CPRIT's Scientific Research and Prevention Programs Committee. CPRIT's statute requires Oversight Committee approval for the appointments. The Nominations Subcommittee will discuss the appointments at its meeting on May 14.

Discussion

Scientific Research and Prevention Programs committee members (also referred to as "peer reviewers") are responsible for reviewing grant applications and recommending grant awards for meritorious projects addressing cancer prevention and research, including product development research. Peer reviewers perform a significant role for the state; all CPRIT grant awards must first be recommended by a Scientific Research and Prevention Programs committee. Individuals appointed to serve as CPRIT's Scientific Research and Prevention Programs committee members must be exceptionally qualified, highly respected, well-established members of the cancer research, product development research, and prevention communities.

Texas Health and Safety Code Section 102.151(a) directs the Chief Executive Officer to appoint members to the Scientific Research and Prevention Programs committees. The CEO's appointments are final once approved by a simple majority of the Oversight Committee. The Nominations Subcommittee charter assigns the subcommittee with the responsibility "to circulate to Oversight Committee members in advance of a public meeting written notification of the committee's intent to make the nomination, along with such information about the nominee as may be relevant."

The nominations subcommittee will review the peer reviewer appointments at its May 14 meeting.



CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

Scientific Research and Prevention Programs Committee (SRPP) Appointments

Appointee	SRPP Assignment	Position & Organization
Academic Research		
Mikala Egeblad, Ph.D.	Cancer Biology panel	Professor and Cancer Center Program Co-Leader Cold Spring Harbor Laboratory Cold Spring Harbor, NY
Prevention		
Thomas E. Novotny, M.D., MPH	Prevention peer review panel	Professor Emeritus of Epidemiology and Biostatistics at the San Diego State University (SDSU) School of Public Health
Deanna GK Teoh, M.D., MS	Prevention peer review panel	Gynecologic oncologist at the University of Minnesota

BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors.
Follow this format for each person. **DO NOT EXCEED FIVE PAGES.**

NAME: Mikala Egeblad

eRA COMMONS USER NAME (credential, e.g., agency login): EGEBLADM

POSITION TITLE: Professor

EDUCATION/TRAINING (*Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable. Add/delete rows as necessary.*)

INSTITUTION AND LOCATION	DEGREE (if applicable)	Completion Date MM/YYYY	FIELD OF STUDY
University of Copenhagen, Denmark	B.S.	01/1993	Medicine
University of Copenhagen, Denmark	M. Sc.	04/1996	Human Biology
University of Copenhagen/Danish Cancer Center, Denmark	Ph. D	02/2000	Health Sciences
University of California, San Francisco	Post Doc	01/2009	Cancer Biology

A. Personal Statement

My research is focused on investigating how interactions between cancer cells and their microenvironment regulate the metastatic spread and therapy responses of cancer. I employ mouse models of cancer and organotypic culture systems. I have developed *intravital microscopy techniques* that allow observation and quantification of cancer and immune cell behaviors in primary tumors and their metastasis in living mice. I use intravital imaging with many other technologies to study how innate immune cells influence cancer. This research has led to several discoveries. First, we demonstrated that factors from the host cells—including matrix metalloproteinase 9 and chemokine (C-C motif) receptor 2—can promote tumor resistance to chemotherapeutic drugs (Nakasone et al., 2012, *Cancer Cell*). These findings predict that co-targeting innate immune cells during chemotherapy can improve drug responses. Second, we identified a novel mechanism by which cancer cells can hijack immune cells to promote progression: using intravital imaging, we discovered that triple negative breast cancer cells activate neutrophils to form metastasis-promoting neutrophil extracellular traps (NETs). We developed nanoparticles that can digest the NETs *in vivo* and showed that these inhibit metastasis (Park et al., 2016, *Science Translational Medicine*). Following up, we discovered that when NETs are activated as part of a sustained inflammatory response they can drive re-initiation of proliferation of quiescent, disseminated tumor cells. Mechanistically, proteases bound to the NETs remodel the ECM, including laminins, to activate integrin signaling in the cancer cells (Albregues et al., 2018, *Science*). In collaboration with Dr. Johannes Yeh, we generated an antibody (Ab28) against NET-remodeled laminin, which could detect NET-remodeled laminin on tissue sections and by intravital imaging, and importantly, it significantly reduced metastasis mediated by NETs. Our third line of work has been focused on reprogramming the tumor microenvironment so it becomes tumor suppressive instead of supportive. Monocytes/macrophages are recruited to tumors and are polarized (*i.e.*, differentiated) into tumor-associated macrophages (TAMs). TAMs promote tumor growth and metastasis and inhibit cytotoxic T cells. Yet, macrophages treated with the bacterial component lipopolysaccharide (LPS) together with the cytokine interferon gamma (IFN γ) can be polarized so they secrete cancer cell-killing nitric oxide. LPS can cause sepsis, but we discovered that a synthetic LPS derivative used in vaccines, monophosphoryl lipid A (MPLA), when combined with IFN γ can activate macrophages isolated from patients with metastatic cancer to kill the same patients' cancer cells *in vitro*. Injecting MPLA with IFN γ directly into mouse models of metastatic breast or ovarian cancer caused repolarization of the TAMs, reduced tumor growth, and offered almost complete protection from the development of metastasis (Sun et al., *bioRxiv*, 2020.07.13.200477). This work highlights the potential for activating the innate immune system to prevent and treat metastasis.

- a) Nakasone, E.S., et al. (2012). Imaging tumor- stroma interactions during chemotherapy reveals contributions of the microenvironment to resistance. *Cancer Cell*, 21, 488-503. PMID: PMC3332002.

- b) Park, J., et al. (2016) Cancer cells trigger neutrophils to induce metastasis-supporting extracellular DNA traps. ***Sci Transl Med***, 8, 361ra138. PMID: PMC5550900.
- c) Albregues, J. et al. (2018) Neutrophil extracellular traps produced during inflammation awaken dormant cancer cells in mice. ***Science***, pii: eaao4227. doi: 10.1126/science.aao4227. PMID: PMC6777850.
- d) Sun L., et al. (2020) Activating a collaborative innate-adaptive immune response to control breast and ovarian cancer metastasis. ***BioRxiv***, doi:https://10.1101/2020.07.13.200477.

B. Positions and Honors

Positions and Employment

2006-2009	Assistant Research Anatomist, UCSF, San Francisco, CA
2009-2010	Visiting Assistant Professor, UCSF, San Francisco, CA
2009-2014	Assistant Professor, CSHL, Cold Spring Harbor, NY
2018-2020	Co-chair of CSHL Faculty Advancement Committee for Assistant and Associate Professors
2010-present	Adjunct Assistant/Associate Professor, Stony Brook University, Stony Brook, NY
2014-2021	Associate Professor, CSHL, Cold Spring Harbor, NY
2014-present	Co-Program Leader of the "Signal Transduction" program at CSHL Cancer Center, Cold Spring Harbor, NY
2021-present	Professor, CSHL, Cold Spring Harbor, NY

Consulting

2002-2004	Consultant, Novo-Nordisk A/S, Denmark
2019	Consultant, CytomX, South San Francisco, CA

Selected Awards and Honors

1996	The Danish Medical Research Council, graduate scholarship with Dr. Jäätelä
2000	The Jens Aage and Edith Ingeborg Sørensen's Memorial Foundation, personal award
2001	The Danish Cancer Society, postdoctoral fellowship
2003	California Breast Cancer Research Program, postdoctoral fellowship
2004	The Danish Medical Research Council, postdoctoral fellowship
2004	Prevent Cancer Foundation, postdoctoral fellowship (awarded but declined)
2007	Abstract selected (from 1,229 submitted abstracts) as 1 of 12 abstracts for the American Society for Cell Biology, Annual Meeting Press Book ("Novel & Newsworthy, Top Picks")
2010	Susan G. Komen Foundation, Career Catalyst Grant
2012	Pancreatic Cancer Action Network-AACR Career Development Award
2013	Abstract selected (from 860 submitted abstracts) as 1 of 12 abstracts for the American Society for Cell Biology, Annual Meeting Press Book ("Novel & Newsworthy, Top Picks", <i>Declined due to conflict with publication</i>)
2014	U.S. Department of Defense (DoD) Breast Cancer Program, Era of Hope Scholar Award
2017	James M. and Cathleen D. Stone Faculty Award for a significant research accomplishment by an Assistant or Associate Professor at CSHL
2017	The Pershing Square Sohn Prize for Young Investigators in Cancer Research
2018	The Suffrage Science Award
2019	The Winship Herr Faculty Teaching Award for excellence in teaching at CSHL

Selected service

Selected advisory boards/executive committees:

2003	Invited Member of NCI workshop, "The Early Reproductive Events and Breast Cancer"
2010, -14, -18	Member of the Education Committee for the Education Sessions and Methods Workshops, AACR Annual Meetings in 2011, 2015, 2019
2012	Invited participant of "NCI Breast Cancer Models Summit", Philadelphia, PA
2012-2017	Member of the Executive Committee of the Watson School of Biological Sciences, CSHL
2016	Member of the AACR Tumor Microenvironment Nominating Committee
2017-present	Member of the External Advisory Board for "Memorial Sloan Kettering Cancer Center (MSKCC) Precision Medicine Center", NIH U54 Project (PI: Dr. Scott Lowe, MSKCC)
2018-present	Member of the Admissions Committee of the Watson School of Biological Sciences, CSHL, Cold Spring Harbor, NY
2019-present	Chairperson Elect, the AACR tumor microenvironment working group

Memberships: AACR (2002-), American Society for Cell Biology (ASCB, 2002-), American Association of Immunologists (AAI, 2009-), The New York Academy of Sciences (2014-), American Association for the Advancement of Science (2017-)

Editorial boards: Advisory Editor, *The Journal of Experimental Medicine*, *Cancer Cell*

Journal reviewer, selected: *Nature*, *Nature Cancer*, *Nature Cell Biology*, *Nature Communications*, *Cancer Discovery*, *Cell*, *Cell Reports*, *Cancer Research*, *Oncogene*, *Proceedings of the National Academy of Sciences*, *Science Translational Medicine*

Grant reviewer: Susan G. Komen (2013, 2014), Breast Cancer Alliance (2014, 2016), Worldwide Cancer Research foundation (2014), AACR Pancreatic Cancer Career Development Award (2015-16), Cancer Research UK (2018)

Study section member: Ad hoc member, NIH TME study section (February 2015); Ad hoc member, DoD Breast Cancer Research Program Integration Panel (September 2016); Ad hoc member, NIH DT study section (February 2018)

Conference organizer: Co-organizer of the Keystone Symposia on “Plasticity within the Tumor Microenvironment” (2017) and “Lymphocytes and their Roles in Cancer” (2018); Lead-organizer of Banbury meeting on “Diverse Functions of Neutrophils in Cancer” (2018); Organizer of Virtual Banbury meeting on “Neutrophils in COVID-19” (2020).

C. Contributions to Science

I have made contributions to four areas of research on the crosstalk between cancer cells and the microenvironment, as outlined below.

1. Intravital imaging of tumor-stroma interactions

My most exciting technical accomplishments are in studies of the dynamics of the tumor microenvironment. When I began my postdoctoral training, there were no technologies available for observing cancer cells interacting with their microenvironment. I custom built a spinning disk confocal microscope, allowing imaging of more tissue components feasible than with other microscopes at the time.

Our intravital imaging techniques were critical for 1) comparing and contrasting the behaviors of stromal cells in different tumor regions; 2) identifying suppressive behaviors of innate immune cells on T cells in breast cancer; 3) demonstrating that the microenvironment can be targeted to enhance therapy response; and 4) showing that aggressive cancer cells induce neutrophil extracellular traps (NETs) when they disseminate.

- Egeblad, M.*, Ewald, A.J.*, Askautrud, H.A., Truitt, M.L., Welm, B.E., Bainbridge, E., Peeters, G., Krummel, M.F., and Werb, Z. (2008). Visualizing stromal cell dynamics in different tumor microenvironments by spinning disk confocal microscopy. **Dis Model Mech**, 1, 155-167. **These authors contributed equally.* See also Editors' Choice, *Science* 2008, 322, 506. PMCID: PMC2562195.
- Engelhardt, J.J., Boldajipour, B., Beemiller, P., Pandurangi, P., Sorenson, C., Werb, Z., Egeblad, M., and Krummel, M.F. (2012). Marginating dendritic cells of the tumor microenvironment cross-present tumor antigens and stably engage tumor-specific T cells. **Cancer Cell**, 21, 402-417. PMCID: PMC3311997. Recommended by F1000Prime.
- Nakasone, E. S., Askautrud, H. A., and Egeblad, M. (2013). Live imaging of drug responses in the tumor microenvironment in mouse models of breast cancer. **J Vis Exp**, 73, doi: 10.3791/50088. PMCID: PMC3639729.
- Fein, M. R., and Egeblad, M. (2013). Caught in the act: revealing the metastatic process by live imaging. **Dis Model Mech**, 6, 580-93. PMCID: PMC3634643.

2. Host responses driving metastasis and lung inflammation

Neutrophil extracellular traps (NETs) are pathogen-trapping structures generated by the neutrophil expelling its DNA with associated proteolytic enzymes (e.g., neutrophil elastase and matrix metalloproteinase 9). Using intravital imaging, we discovered that metastatic cancer cells can trigger NET formation, which in turn promote invasion and metastasis by concentrating protease activity. We documented that NETs are present in metastatic human breast tumors. Following up, we showed that when NETs are activated as part of a sustained inflammatory response (e.g., caused by tobacco smoke exposure), this can drive re-initiation of otherwise quiescent disseminated tumor cells. Mechanistically, NETs function to concentrate extracellular proteases so that they efficiently generate an integrin-activating epitope on laminin. Most recently, we discovered that NETs are formed during severe COVID-19, and found in lung, in blood, and in micro-thrombi.

Our studies have revealed novel mechanisms for how inflammatory cells enhance metastasis, with major implication for prevention of late metastatic recurrence as well as other diseases involving lung inflammation.

- Park, J., Wysocki, R.W., Amoozgar, Z., Maiorino, L., Fein, M.R., Jorns, J., Schott, A.F., Kinugasa-Katayama, Y., Lee, Y., Won, N.H., Nakasone, E.S., Hearn, S.A., Küttner, V., Qiu, J., Almeida, A.S., Perurena, N., Kessenbrock, K., Goldberg M.S., and Egeblad, M. (2016) Cancer cells trigger neutrophils to induce metastasis-supporting extracellular DNA traps. **Sci Transl Med**, 8, 361ra138. PMCID: PMC5550900.

Selected for the cover. See also Research Highlights, Nature Reviews Cancer 2016, 16, 757 & *Research Highlights, Nature Reviews Drug Discovery* 2016, 15, 822. Recommended by F1000Prime.

- b. Albregues, J., Shields, M.A., Ng, D., Park, C.G., Ambrico, A., Poindexter, M., Upadhyay, P., Uyeminami, D., Pommier, A., Küttner, V., Bružas, E., Maiorino, L., Bautista, C., Carmona, E.M., Gimotty, P.A., Fearon, D.T., Chang, K., Lyons, S.K., Pinkerton, K., Trotman, L.C., Goldberg, M.S., Yeh, J.T.-H., Egeblad, M. (2018) Neutrophil extracellular traps produced during inflammation awaken dormant cancer cells in mice. **Science**, pii: eaao4227. doi: 10.1126/science.aao4227. PMID: PMC6777850. *Comments in Science* (2018) 361:1314-1315; *Immunity* (2018) 49: 798-800; *Nature Reviews Cancer* (2018), 18, 722-23; *Nature Reviews Immunology* (2018), 18, 665; *Cancer Discovery* (2018) DOI: 10.1158/2159-8290.CD-RW2018-171. Recommended by F1000Prime.
- c. Pommier, A., Anaparthi, N., Memos, N., Kelley, Z., Gouronnec, A., Yan, R., Auffray, C., Albregues, J., Egeblad, M., Iacobuzio-Donahue, C.A., Lyons, S.K., Fearon, D.T. (2018) Unresolved endoplasmic reticulum stress engenders immune resistant, latent pancreatic cancer metastases **Science**, pii: eaao4908. doi: 10.1126/science.aao4908. PMID: PMC6547380.
- d. Barnes, B.J., Adrover, J.M., Baxter-Stoltzfus, A., Borczuk, A., Cools-Lartigue, J., Crawford, J.M., Daßler-Plenker, J., Guerci, P., Huynh, C., Knight, J.S., Loda, M., Looney, M.R., McAllister, F., Rayes, R., Renaud, S., Rousseau, S., Salvatore, S., Schwartz, R.E., Spicer, J., Yost, C.C., Weber, A., Zuo, Y., Egeblad, M. (2020) Targeting potential drivers of COVID-19: Neutrophil extracellular traps. **J Exp Med**, 217:e20200652. doi: 10.1084/jem.20200652.

3. The role of the microenvironment in adaptive drug resistance

In advanced cancer, chemotherapy can slow disease progression, but resistance almost always develops. Using intravital imaging, we revealed that doxorubicin treatment led to monocyte recruitment. Importantly, in host mice lacking CCR2, monocyte infiltration was greatly reduced and the response to the chemotherapeutic drugs doxorubicin and cisplatin lasted significantly longer than in normal mice.

Our work revealed that targeting factors in the microenvironment, specifically CCR2, improves responses to already existing cancer drugs. This prediction is currently being tested in clinical trials, with positive preliminary results reported for pancreatic cancer.

- a. Nakasone, E.S., Askautrud, H.A., Kees, T., Parks, J.-H., Plaks, V., Ewald, A.J., Fein, M., Rasch, M.G., Tan, Y.X., Qiu, J., Park, J., Sinha, P., Bissell, M., Frengen, E., Werb, Z., and Egeblad, M. (2012). Imaging tumor-stroma interactions during chemotherapy reveals contributions of the microenvironment to resistance. **Cancer Cell**, 21, 488-503. PMID: PMC3332002. *Selected for the cover. See also Research Highlights: Nature*, 485, 282. Recommended by F1000Prime.
- b. Sounni, N.E., Dehne, K., van Kempen, L.C.L., Egeblad, M., Affara, N.I., Cuevas, I., Wisen J., Junankar, S., Korets, L., Lee, J., Shen, J., Morrison, C.J., Overall, C. M., Krane, S.M., Werb, Z., Boudreau, N., and Coussens, L.M. (2010). Stromal Regulation of Vessel Stability by MMP14 and TGFβ. **Dis Model Mech**, 3, 317-32. PMID: PMC2860851.
- c. Fein, M.R., He, X.Y., Almeida, A.S., Bružas, E., Pommier, A., Eberhardt, A., Fearon, D.T., Wilkinson, J.E., Santos, C.O.d., Egeblad, M. (2020). Cancer cell CCR2 orchestrates suppression of the adaptive immune response. **J Exp Med**, 217 (10): e20181551.

4. The role of matrix metalloproteinases in tumor progression

Matrix metalloproteinases (MMPs) are extracellularly acting proteases. In a review on the roles of MMPs in cancer (cited >4,000 times), I proposed the viewpoint, novel at the time, that MMPs have tumor-inhibiting functions beyond their more recognized cancer promoting roles. This more complex view of the functions of MMPs is now widely accepted. Over the years, we have studied MMP2, MMP9, MMP13, and MMP14 in breast cancer, e.g., showing in mouse models of breast cancer that MMP9 has different effects on vascular structure and tumor initiation depending on which oncogenic pathways are driving the tumors. Most recently, we showed that the activity of MMP9 on NETs was critical for the pro-metastatic effects of NETs (publication 2b above).

- a. Egeblad, M. and Werb, Z. (2002). New functions for the matrix metalloproteinases in cancer progression. **Nat Rev Cancer**, 2, 161-174. PMID: 11990853.
- b. Egeblad, M., Shen, H.-C. J., Behonick, D.J., Wilmes, L., Eichten, A., Korets, L., Kheradmand, F., Werb, Z., and Coussens, L.M. (2007). Type I collagen is a modifier of matrix metalloproteinase 2 function in murine skeletal development. **Dev Dyn**, 236, 1683-93. **Selected for the cover.** PMID: PMC2581616.
- c. Nielsen, B.S., Egeblad, M., Rank, F., Askautrud, H.A., Pennington, C., Edwards, D.R., Christensen, I.J., Werb, Z., and Lund, L.R. (2008). Matrix Metalloproteinase 13 is induced in fibroblasts in polyomavirus middle T antigen-driven mammary carcinoma without influencing tumor progression. **PLoS One**, 3, e2959.

PMCID: PMC2493034.

- d. Park, J.-H., Rasch, M.R., Qiu J., Lund I.K., Egeblad, M. (2015). Presence of insulin-like growth factor binding proteins correlates with tumor-promoting effects of matrix metalloproteinase 9 in breast cancer. *Neoplasia*, 17, 421-33. PMCID: PMC4468371.

Complete List of Published Work in My Bibliography:

<http://www.ncbi.nlm.nih.gov/sites/myncbi/1zAxVPPoJ1jk3/bibliography/47921113/public/?sort=date&direction=ascending>

D. Additional Information: Research Support and/or Scholastic Performance

1R01CA237413-01A1, NIH/NCI Egeblad (PI) 03/01/2020 – 02/28/2025
Identifying the pro-metastatic mechanisms of neutrophil extracellular traps
The goal of this project is to identify mechanism by which neutrophil extracellular traps activated during lung inflammation promote metastasis
Role: Principal Investigator

W81XWH-20-1-0753, Department of Defense (Egeblad/Van Aelst) 08/01/2020 – 07/31/2023
Targeting Neutrophil Extracellular Traps to Prevent Breast Cancer Metastasis Caused by Stress
The overall objective of this proposal is to identify the key cellular mechanisms by which NETs drive stress-induced breast cancer metastasis.
Role: Partnering Principal Investigator

5P01CA013106-49, NIH/NCI Stillman (PI) 02/20/2018 – 01/31/2023
CSHL Cancer Research Center – Core C: Imaging: From Super-Resolution to Whole Animal
Salary support for directing the Imaging Core of the CSHL Cancer Research Center Program Project. The Core assists program investigators with small animal and live cell imaging, and with histopathology.
Role: Co-Core Director

5P30CA045508-33, NIH/NCI Tuveson (PI) 08/01/2016 – 07/31/2021
Cold Spring Harbor Laboratory Cancer Center Support Grant
Salary support for co-leading a program of investigators who study the role of signal transduction and cell-cell communication in cancer as part of the CSHL Cancer Center.
Role: Program Co-Leader

Thompson Family Foundation Tuveson (PI) 03/06/2017 – 03/05/2021
Targeting Pancreas Cancer
This project aims to address three areas of unmet medical need in pancreatic cancer by developing: (1) new methods for early detection; (2) an effective therapy for locally advanced tumors as a bridge to surgery; and (3) novel therapies to control advanced, currently incurable tumors.
Role: Project Co-Principal Investigator

5R01NS116353-02, NIH/NINDS Heller (PI) 03/15/2020 – 12/31/2024
Tumor-selective delivery approaches for Medulloblastoma
The goal of this project is to use intravital imaging with nanoparticles to selectively deliver cancer treatment to medulloblastoma.
Role: Co-Investigator

Thomas E. Novotny, MD MPH

Dr. Novotny is Professor Emeritus of Epidemiology and Biostatistics at the San Diego State University (SDSU) School of Public Health. He is a graduate of the University of Nebraska Medical Center (MD 1973) and Johns Hopkins Bloomberg School of Public Health (MPH Epidemiology 1992). He served as a CDC epidemiologist in the Office on Smoking and Health and as Deputy Assistant Secretary for Health in the US Department of Health and Human Services. He co-directed the Joint PhD program in Global Health at SDSU/UCSD from 2009-2015, and he has done extensive research on tobacco and the environment. In 2010, he founded the Cigarette Butt Pollution Project, a research, educational, and advocacy non-profit organization that addresses tobacco's impact on the environment.

Deanna GK Teoh, MD, MS

I am a gynecologic oncologist at the University of Minnesota. I received my medical degree at the Medical College of Wisconsin in 2004, then completed a residency in Obstetrics & Gynecology at University of California San Francisco, and a fellowship in Gynecologic Oncology at Duke University in 2011. I earned a Master's in Clinical Research from University of Minnesota in 2018. My research focus is prevention of cervical and other HPV-associated cancer through optimized screening and increasing HPV vaccination coverage. I specifically have interest in improving communication about healthcare recommendations to the general population using novel communication technology. I was part of the ASCCP treatment working group for development of the 2020 risk-based cervical cancer screening management guidelines, and am the Society of Gynecologic Oncology representative for the national HPV Roundtable. My research has been funded by various organizations, including the NIH and Department of Defense.



CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

MEMORANDUM

TO: OVERSIGHT COMMITTEE MEMBERS
FROM: WAYNE ROBERTS, CHIEF EXECUTIVE OFFICER
SUBJECT: GEOGRAPHIC DIVERSITY ADVISORY COMMITTEE
DATE: MAY 10, 2021

BACKGROUND

Pursuant to instructions from Presiding Officer Margo I contacted the institutions of higher education eligible for the Texas Regional Excellence in Cancer (TREC) awards for nominations to a new Geographic Diversity Advisory Committee. This group will advise the Oversight Committee and staff on these universities' special needs and challenges in developing cancer research capacity in locations far away from the cancer research centers in the major metropolitan areas. Each of these universities is located 100 miles or more from a National Cancer Institute Designated Center in Houston, Dallas, or San Antonio.

RECOMMENDATION

The Oversight Committee approve the following individuals to the Geographic Diversity Advisory Committee.

Dr. Rob Kirken
Dean of Science & Professor
Department of Biological Sciences
The University of Texas at El Paso

Sarah Williams-Blangero, Ph.D.
HEB Distinguished Chair in Diabetes and Genomics
Chair, Department of Human Genetics
Director, South Texas Diabetes and Obesity Institute
School of Medicine
The University of Texas Rio Grande Valley

Joseph F. Woelkers, M.A.
Executive Vice President Administration
Chief Business Officer
The University of Texas at Tyler

Dr. Ken Ramos

Executive Director of the Institute of Biosciences & Technology
Assistant Vice Chancellor for Health Services
Associate Vice President for Research
Texas A&M University System

Dr. Joe Heppert
Vice President for Research and Innovation
Texas Tech University

Min Kang, Pharm.D.
Interim Senior Vice President for Research and Professor, Department of Pediatrics,
Scholl of Medicine Cancer Center
Texas Tech University Health Sciences Center

Dr. Rajkumar Lakshmanaswamy
Dean, Graduate School of Biomedical Sciences
Texas Tech University Health Sciences Center El Paso

Daniel Romo, Ph.D.
Schotts Professor of Chemistry and Biochemistry
Baylor University

Dr. Peter Davies, MD, PhD is Professor and Director of the Center for Translational Cancer Research at the Texas A&M University Institute of Biosciences and Technology in Houston. He also serves as interim Head of the Department of Translational Medical Sciences, Texas A&M College of Medicine. Dr. Davies has had a long-standing interest cancer therapeutics and academic drug discovery. Following physician-scientist training at the University of Miami, he completed 4 years of post-doctoral training at the National Cancer Institute before joining the faculty of the University of Texas Medical School in Houston. He spent more than 30 years at UT-Houston rising to the rank of Professor of Pharmacology and Medicine, Executive Vice-President for Research and Provost of the Health Science Center. In 2011 he moved to Texas A&M University to lead a program in cancer-related drug discovery research at the A&M Institute of Biosciences and Technology. Dr. Davies is grateful for the generous research grant support that he and his colleagues have received from CPRIT and is committed to supporting CPRIT in its goal of the developing advances in the prevention and treatment of cancer that will benefit the citizens of Texas, the nation and the world.

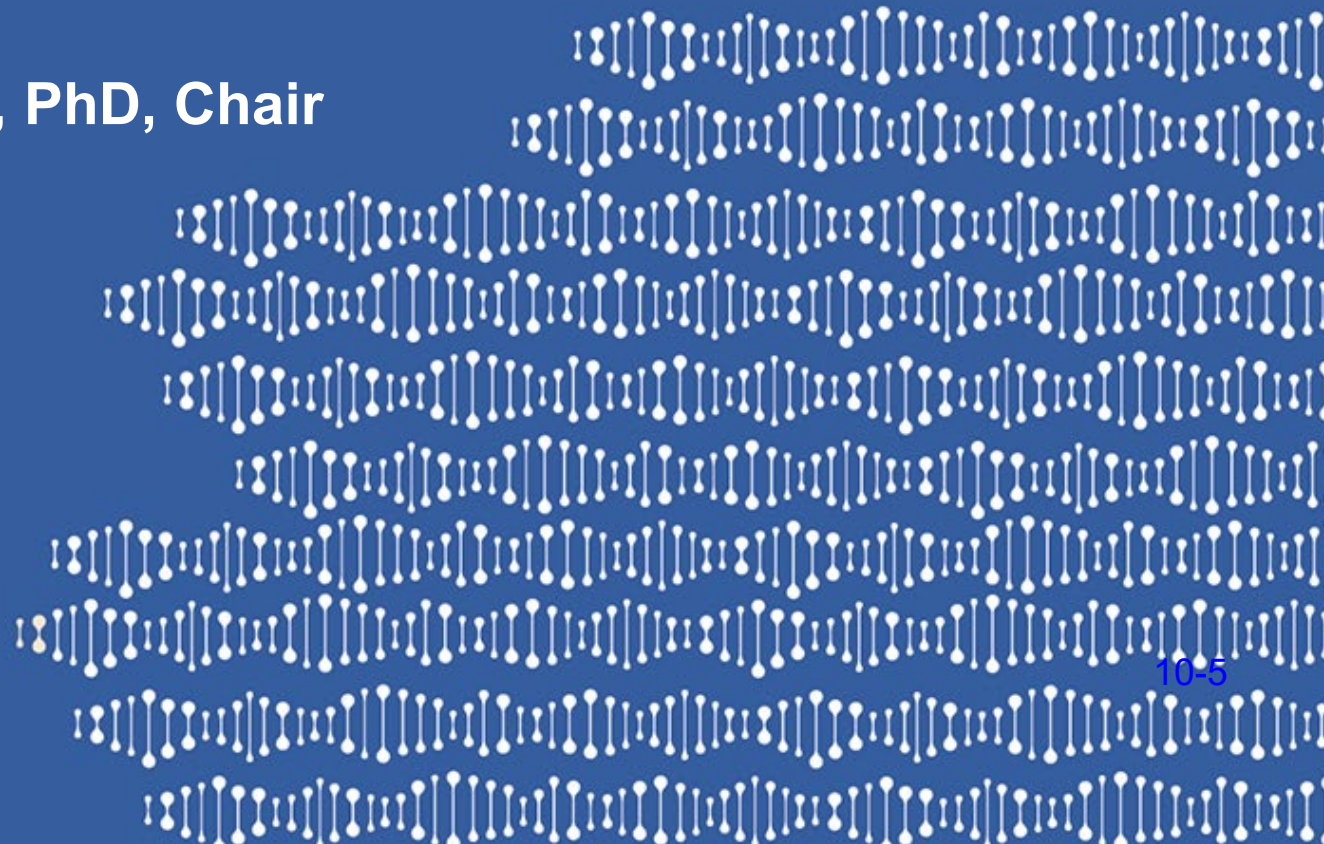




CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

University Advisory Committee 2021 Annual Report

Presented By:
Peter Davies MD, PhD, Chair
May 19, 2021



University Advisory Committee (UAC) – Membership FY20 - 21

Peter Davies, MD, PhD, Texas A&M Health Science Center, CHAIR

C. Kent Osborne, MD, Baylor College of Medicine, PAST CHAIR

Carlos Arteaga, MD, UT Southwestern, VICE CHAIR

Abbey B. Berenson, MD, MMS, PhD, UT Medical Branch

Subhash C. Chauhan, Ph.D. UT Rio Grande Valley

Giulio F. Draetta, MD, PhD, MD Anderson Cancer Center,

Joseph Heppert, PhD, Texas Tech

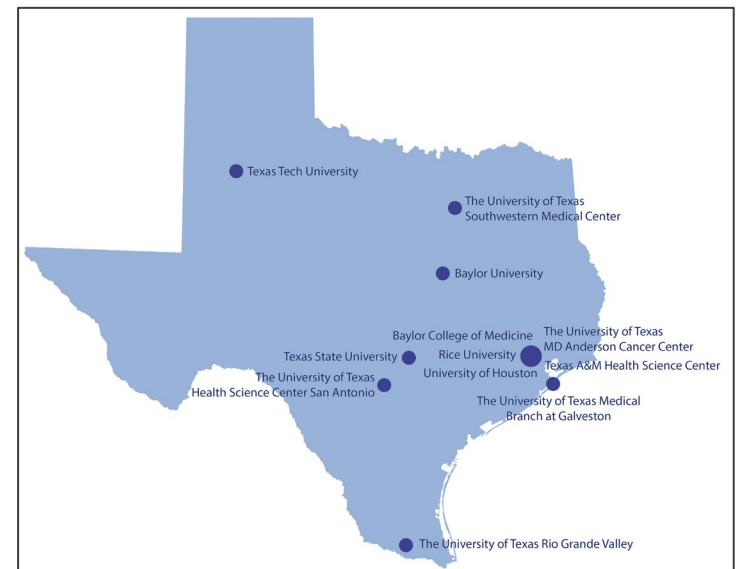
Walter Horton, PhD, Texas State University

Ruben Mesa, MD, UT HSC – San Antonio

Claudia Neuhauser, PhD, Univ of Houston

Yousif Shamoo, PhD, Rice University

John Wood, PhD, Baylor University



UAC Meetings and Discussions

2020 / 2021

Meetings

November 10, 2020; March 2, 2021; April 30, 2021

Topics of Discussion

CPRIT2.0 – FY20-21 an Inflection Point

1. Review of Current Academic Research Programs
2. Challenges

Summary of Recommendations

Current Programs

1. Balanced and very effective portfolio of research programs
2. Opportunity for Fine Tuning

Challenges - 3 Major Challenges / Opportunities

1. Regional Impact
2. Translation to Clinical Applications
3. Translation to Commercialization

10-7



Academic Research Program

Principles and Priorities

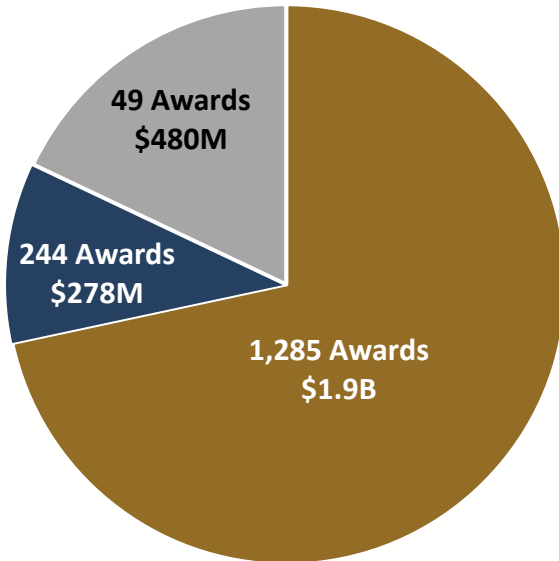
Established Principles:

- Scientific excellence and impact on cancer
- Increasing the life sciences infrastructure
- Recruitment of outstanding cancer researchers to Texas
- Investment in core facilities
- A broad range of innovative, investigator-initiated research projects
- Implementation research to accelerate the adoption and deployment of evidence-based prevention and screening interventions.
- Computational biology and analytic methods
- Childhood cancers
- Hepatocellular cancer
- Expand access to innovative clinical trials

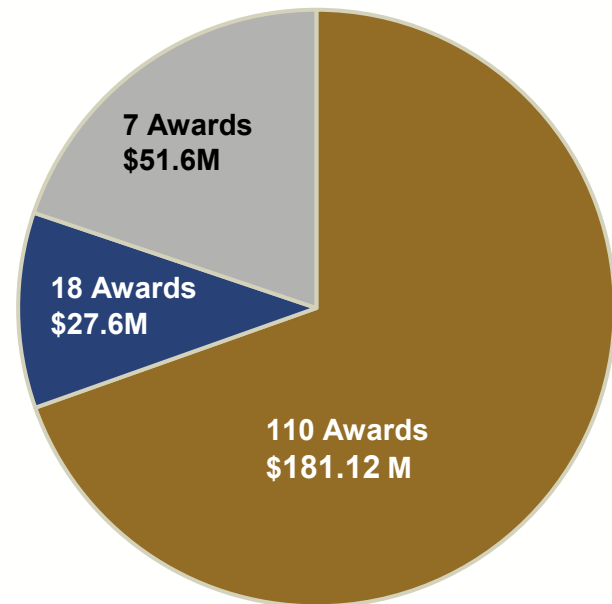


CPRIT Funding by Program

Cumulative Funding



FY20 Funding



Academic Research Prevention Program Product Development

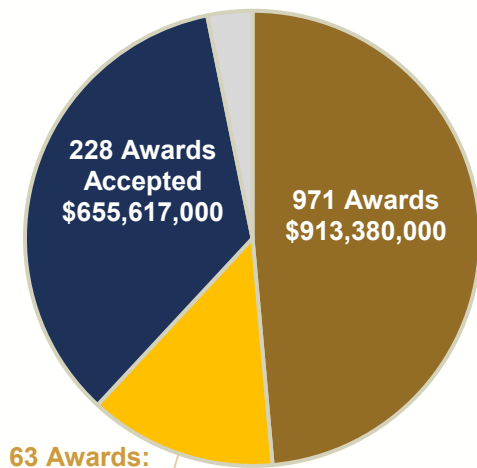
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CPRIT Academic Research

- Cumulative Funding

23 Awards: \$60,050,000



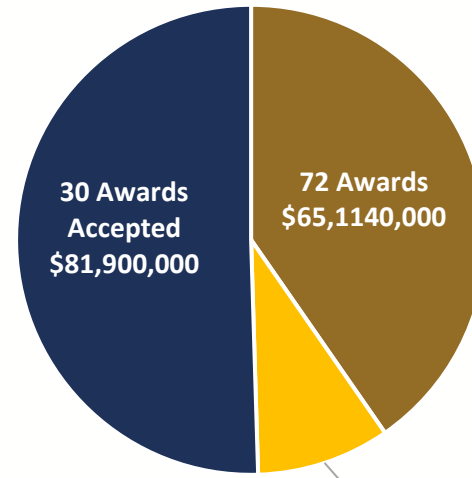
■ Investigator Initiated Research Awards

■ Core Facility Research Awards

■ Scholar Awards

■ Research Training Awards

FY20 Funding



■ Investigator Initiated Research Awards

■ Core Facility Support Awards

■ Scholar Awards

\$14,820,000
4 Awards



CPRIT Academic Research FY 2020

NOTABLE ACADEMIC RESEARCH PROGRAM HIGHLIGHTS IN FY2020

- CPRIT Academic Research Program awards \$182 M in research and recruitment awards to 21 Texas Universities
- 31 CPRIT recruitment awards to 9 Texas institutions
- First Early Clinical Investigators Awards awarded to clinical faculty at Baylor, MD Anderson and UT Southwestern
- \$13 M for statewide Collaborative Action Program to address the liver cancer in Texas.
- Texas Institutions receiving first CPRIT award in 2020

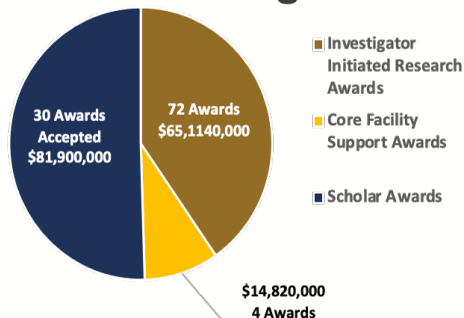
Texas A&M Corpus Christi - first CPRIT award

Texas A&M Engineering Experiment Station - first CPRIT Scholar Award

Texas Tech University Health Sciences Center Amarillo - first Core Facility Support Award

Texas Tech University School of Veterinary Medicine - first CPRIT Scholar Award

FY20 Funding



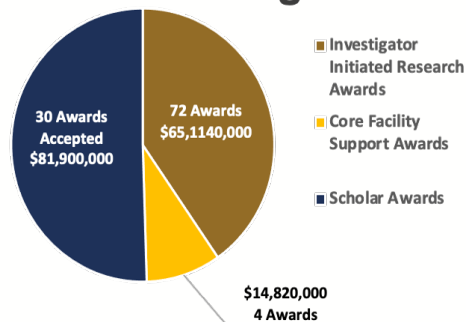
CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

Investigator initiated research awards FY20

Mechanism	Applications	Recommended for funding	Total Funding Recommended	Success Rate
Individual Investigator Research Awards (IIRA)	265	36	\$32,039,552	14%
IIRA for Childhood Cancers	55	6	\$7,376,570	11%
IIRA for Prevention and Early Detection	38	3	\$3,270,868	8%
IIRA for Clinical Translation	29	4	\$6,140,782	14%
CAP to Reduce Liver Cancer Mortality in Texas	16	3	\$7,407,804	19%
Core Facilities Support Award	18	4	\$14,821,043	22%
Early Clinical Investigator Award	8	4	\$5,991,545	50%
High Risk/High Impact Research Award	107	17	\$4,245,038	16%
FY 20 Total	536	77	\$81,293,202	

Infrastructure -Scholar Awards FY 20/21

FY20 Funding



FY2020 Recruitment Application Outcomes

Mechanism	#	Recommended For Funding	Success Rate	Funding	Acceptance Status		
					Accepted	Declined	Pending
FY 20 Recruitment Total	84	41	49%	\$99,971,334	31	8	2
Established Investigators	20	12	60%	\$46,071,334	6	4	2
Rising Stars	12	4	33%	\$12,000,000	3	1	0
First-Time, Tenure Track	52	25	48%	\$41,900,000	22	3	0

Prestigious National Award Recognition of CPRIT Grantees

Prestigious National Awards	Scholars	Researchers
Nobel Laureate	1	
Lasker Award Recipients	2	
National Academy of Engineering	1	
National Academy of Sciences (NAS)	7	11
National Academy of Medicine (NAM)	5	17
Investigators Howard Hughes Medical Institute (HHMI)	3	9
NCI Outstanding Investigator Awardees	2	6

Recruitment Awards Impact Data 2010 - 2020

Mechanism	# Awards	CPRIT FUNDING	FOLLOW-ON-FUNDS	Publications	Patents Filed / Granted
Established Investigators	44	\$271,880,000	\$227,116,523	507	181/2
Rising Stars	19	\$73,970,000	\$51,228,399	206	0
First-Time, Tenure-Track	147	\$291,890,000	\$198,342,730	573	33/6
TOTALS	210	\$637,740,000	\$476,687,652	1,286	214/8

Institutions: (20)

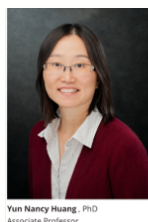
Baylor College of Medicine
 Baylor University
 Rice University
 Texas A&M University
 Texas A&M HSC
 Texas A&M Engineering Experiment Station
 Texas Tech University,
 Texas Tech University HSC - El Paso
 The Methodist Hospital Research Institute
 The University of Houston

The University of Texas System
 The University of Texas at Arlington
 The University of Texas at Austin
 The University of Texas at Dallas
 The University of Texas Health Center at Tyler
 The University of Texas HSC at San Antonio
 The University of Texas HSC at Houston
 The University of Texas M.D. Anderson Cancer Center
 The University of Texas Medical Branch at Galveston
 The University of Texas Southwestern Medical Center



Timeline for a Young Investigator Recruitment Awardee

Texas A&M Health Science Center



Yun Nancy Huang, PhD
Associate Professor

Yun Nancy Huang

**CPRIT
Scholar**

- CPRIT Recruitment Award
- Tenure-track Assistant Professor at TAMU

- AHA Innovative Project Award (PI)
- NIH U01ES026719 (Co-I)

- NIH R01HL134780 (PI)
- ACS Research Grant (PI)
- CPRIT Individual Investigator Award (co-I)
- TMC DDC See Grant
- 13 papers published in top journals;
- 1 patent application: Licensed to Refuge Inc.

- NIH R21GM138824 (PI)
- BCM Lymphoma SPORE Seed Grant
- TAMU T3 Grants (Co-I)
- 10 papers published in top journals;
- 1 patent application: Licensed to XimBio Inc.

Milestones



- "Scientist to Watch" feature by The Scientist Magazine

- Dunn Foundation (PI)
- CTEHR pilot grant (PI)
- ACS Research Grant (Co-I)
- NIH R01DK112368 (Collaborator)
- CPRIT HIHR (Co-I)
- Rising Star Award from The American Medical Professional Foundation
- 3 papers as senior author in top journals and featured by editors

- NIH R01HL146852 (PI)
- Cancer Fighter of Houston Foundation Award (PI)
- CPRIT HIHR (Co-I)
- NIH R01CA232017 (Co-I)
- NIH R01GM112003 (Co-I)
- TAMU COM Research Excellence Award;
- Outstanding research award in Gordon Research Conference;
- Promotion to Associate Professor with tenure;
- 10 papers published in top journals

- NIH R01CA211773 (PI)
- NIH U01CA217613 (Co-I)
- 4 papers published in top journals;

Collaborators

- Baylor COM
- MDACC
- Rice Univ
- UT Houston
- Texas A&M
- John Hopkins
- UCSD

CPRIT RR140053 – 2014 \$1.8M

Total Research and fellowship grant awards:

Total : \$9.5M (PI: \$8.9M ; Co-PI \$0.5M)

Peer-reviewed papers (since 2014):

52 publications; 23 as senior author

Trainees:

Total 18

(Postdoc 7; Grad students: 3; Visiting Scholar: 8)

Licensed Patents

Total 2

10-13



CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

UAC – Comments & Recommendations Scholars Program

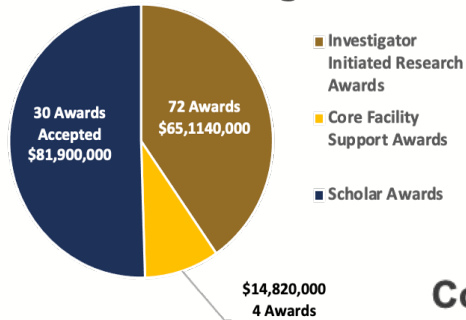
- **“Most important component of CPRIT’s Academic Research Program; “a critical program”**
- **Program has led to the recruitment of exceptional scientists and leaders in cancer research to Texas**
- **The impact goes far beyond the immediate ROI – recruits have had a catalytic presence, establishing new research programs. Impact will be reflected in growth in extramural support over many years**
- **The high success rate reflects the priority of candidates selected by institutions for these awards**
- **Retention has not been a problem - favorable environment and CPRIT programs provide a strong incentive to stay**
- **Program is building strength in cancer research across the State.**

10-14



Infrastructure - Core Facility Support Awards

FY20 Funding



Core Facility awards FY20

Mechanism	Applications	Recommended for funding	Funding	Success Rate
Core Facilities Support Award	18	4	\$14,821,043	22%

Core Facility Awards Impact Data. 2010-2020

Mechanism	#	FUNDING	FOLLOW-ON-FUNDS	Publications	Patents Filed/Granted
Core Facilities Support Awards	51	\$223,220,000	\$381,627,401	515	18/1

Institutions (20)

Baylor College of Medicine
 Baylor Scott and White Health Care
 Texas A&M University HSC - College Station
 Texas A&M University HSC - Houston
 Texas Tech University HSC - Amarillo
 Texas Tech University HSC - Dallas
 Texas Tech University HSC - El Paso
 Texas Tech University HSC - Lubbock

Texas Medical Center Foundation – Houston
 Texas Southern University
 The Methodist Hospital Research Institute
 The University of Houston
 The University of Texas at Austin
 The University of Texas at Dallas
 The University of Texas at San Antonio
 The University of Texas HSC at San Antonio
 The University of Texas HSC at Houston
 The University of Texas M.D. Anderson Cancer Center
 The University of Texas Medical Branch at Galveston
 The University of Texas Southwestern Medical Center



A CPRIT-funded Network of Core Facilities to Support Academic Drug Discovery Research in Texas

Drug Discovery Centers

Texas A&M HSC
Combinatorial Drug Discovery Program
Davies / Stephan

*Repurposing and Combinatorial
Therapeutics*

UT – Austin
Targeted Therapeutics Drug
Discovery & Development Program
Kevin Dalby

Enzymology & Chemistry

UT – San Antonio
The Center for Innovation and Drug
Discovery
Stan McHardy

Medicinal Chemistry

Baylor COM
Preclinical Candidate Discovery Core
Matzuk / Young

Specialized Chemical Libraries



UT – Houston
Cancer Therapeutic Antibody
Lead Optimization Core
Zhiqiang An

Antibody Therapeutics

Texas A&M / BCM
Center for Advanced Microscopy
& Imaging Informatics
Mike Mancini

Imaging Assay Development

Texas Southern Univ (TSU)
Center for Comprehensive PK/PD
& Formulation
Dong Liang

Pre-clinical Development

Specialized Support Core Facilities

Texas Medical Center
Business-Driven Accelerator
for Cancer Therapeutics
Tom Luby

Business Development

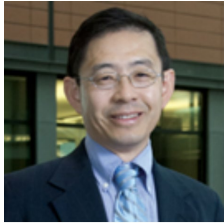
Texas A&M HSC.
High-throughput Flow Cytometry
Margie Moczygemba

Specialized Analytic Systems



The CPRIT Therapeutic Antibody Drug Discovery and Development Core

(RP150551& RP190561, PI: Zhiqiang An, UTHealth-Houston)



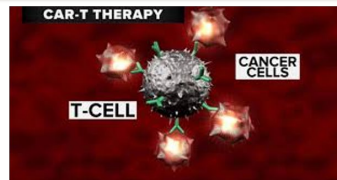
Zhiqiang An

CFSA
Awardee

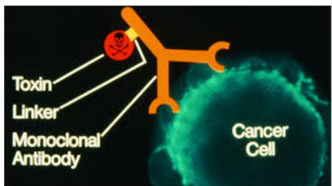
Antibody-based drug modalities



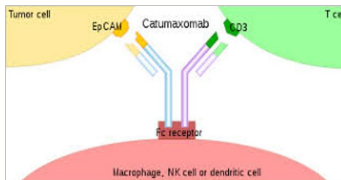
Monoclonal Antibody



CAR-T Cell Therapy



Antibody Drug Conjugate



Bispecific Antibody

Cancer antibody drug discovery projects

- Over **30** antibody drug discovery projects with collaborators across Texas (UTSW, UT-MDACC, UTHealth-Houston, San Antonio, and BCM)
- Targeting major cancer types (breast, colon, AML, liver, ovarian, GBM, lung, and pancreas)

Intellectual properties

- **42** technology invention disclosures
- **45** US and international patent applications filed
- **15** issued patents to date

Licensing deals

- **5** technologies licensed to companies for commercial drug development
- **3** drug candidates are in clinical trials
- **>\$7.5 million** upfront payments
- **>\$149 million** potential milestone payments and minimum royalties

Funding

\$40 million dollars in research funding from NIH CPRIT, US Army, ImmuneOnc Inc. PanaMab Inc., AlaMab Inc., J&J, Merck, Sanofi and others

Publications

>100 peer-reviewed publications in highly competitive journals



CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

UAC – Comments & Recommendations

Core Facilities Program

- **The Core Facilities Program is a very valuable component of the Academic Research Program, building infrastructure within research organizations to support many aspects of cancer research**
- **The Program is providing researchers with ready access to state-of-the-art technologies and expertise in specialized areas of research that are enabling for innovative approaches to cancer research.**
- **As the Program matures there will an increasing need to balance CPRIT's investment in new technologies and new core facilities versus the continued support of highly successful and valuable established core facilities.**
- **The Core Facilities Program can and should play in important role in bridging the gap between basic research and both clinical and commercial applications**

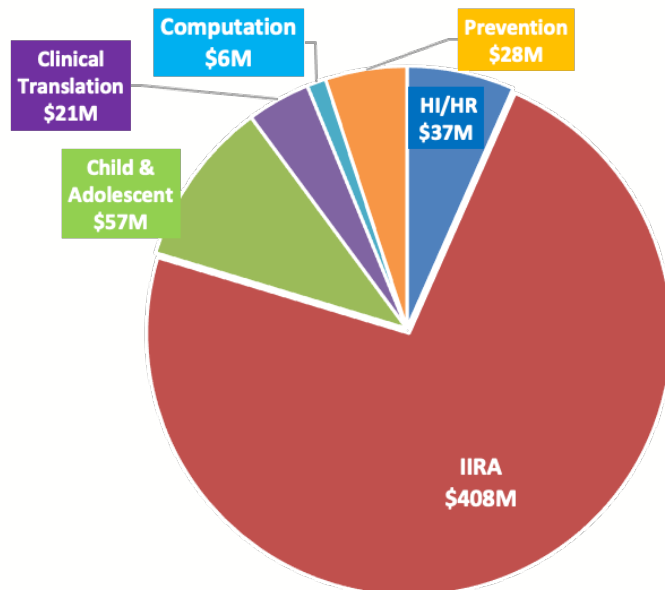
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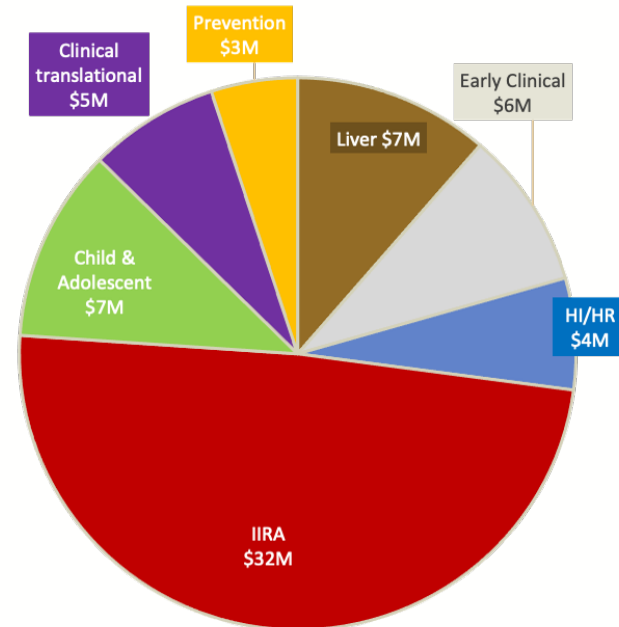
Investigator Initiated Research Program Targeted and Un-Targeted Research Programs

Timeline and Success Rate for Un-targeted and Targeted Individual Investigatoor Research Awards (IIRA)														
	FY 10	FY11	FY12	FY13	FY14	FY15	FY16	FY17	FY18	FY19	FY20	Applications	Funded	Success Rate
Un-Targeted IIRA's														
Individual Investigator Research Award (IIRA)												4176	446	11%
High Impact/High Risk												1252	185	15%
Targeted IIRA's														
IIRA for Cancer in Children and Adolescents												278	44	16%
IIRA for Prevention and Early Detection												259	25	10%
IIRA for Computational Biology												164	8	5%
IIRA for Clinical Translation												116	13	11%
IIRA to Reduce Liver Cancer Mortality												31	4	13%
IIRA for Early Clinical Investigator												8	4	50%

Investigator Initiated Awards 2010 - 20



Investigator Initiated Awards FY20



10-19



Investigator Initiated Research Program

Targeted and Un-Targeted Research Programs Impact

FY2010-2020 Impact Data

Mechanism	Number of Awards	CPRIT Funding	Total Follow-On Funds	Number of Published Publications	Patents Filed/Granted
High-Impact/High-Risk Research Awards	185	\$ 37,020,000.00	\$ 39,900,696.00	233	27/3
Individual Investigator Research Awards	446	\$ 408,460,000.00	\$ 324,431,904.18	1355	82/22
Individual Investigator Research Awards for Cancer in Children and Adolescents	44	\$ 57,200,000.00	\$ 20,031,674.00	90	5/1
Individual Investigator Research Awards for Clinical Translation	13	\$ 21,890,000.00	\$ -	11	0
Individual Investigator Research Awards for Computational Biology	8	\$ 6,600,000.00	\$ -	32	2/0
Individual Investigator Research Awards for Prevention and Early Detection	25	\$ 28,050,000.00	\$ 2,193,353.00	47	4/0
Individual Investigator Research Awards to Reduce Liver Cancer Mortality	4	\$ 9,860,000.00			
Early Clinical Investigator	4	\$ 5,990,000.00			
Totals	729	\$ 575,070,000.00	\$386,557,627.18	1768	120/26

Source: Submitted and Approved Progress Reports

10-20



UAC – Comments & Recommendations

Investigator Initiated Research Awards (IIRA)

- The highest priority should be the quality of the Science – scientific merit and innovation
- The IIRA program should serve as a ‘stepping stone’ to federal grant support –particularly for Early-Stage Investigators.
- A valuable aspect of the IIRA is the opportunity to prioritize underserved areas of cancer research as well as regional issues
- Maintaining a health balance of targeted vs un-targeted research programs will require a regular curation of topics, sunseting some and initiating others

10-21



Challenges – Regional Disparities

RFA R-21.2-TREC

Texas Regional Excellence in Cancer

TREC Program Cycle 1

- Modeled on NIH Centers of Biomedical Research Excellence (COBRE)
- Emphasis on mentored training of talented young investigators
- Insuring access to key infrastructure and cores
- Promoting partnership with established centers of cancer research
- Opportunity for recruitment
- Cycle 1 - Limited to institutions distant from NIH-funded Cancer Centers

RFA Mechanism	# Applications Submitted	Requested Funding
Texas Regional Excellence in Cancer Award	7	\$41,786,641

UAC: The TREC Program can serve as a platform that can be refined, based on outcomes, to extend the reach of CPRIT's cancer research programs to underserved regions of the State



Challenges – Promoting Clinical and Translational Research

How to Bolster Clinical and Translational Research

Early Clinical Investigator (ECI) Award (2020)



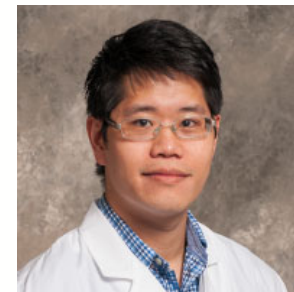
Premal Lulla, M.D.
Baylor COM
BCM stem cell transplantation program
Planning trial to test novel T cell therapies for treatment of AML



Nicolas Palaskas, M.D.
UT M.D. Anderson CC
A clinical cardiologist specializing in cardio-oncology
Planning trials to mitigate cardiac toxicity associated with cancer immune therapies.



Chad Tang, M.D.
UT M.D. Anderson CC
A radiation oncologist conducting a trial to evaluate radiation therapy for low volume metastatic cancer.



David Hsieh, M.D.
UT Southwestern
Planning trial of a novel approach to augment the responses of liver cancers to checkpoint immunotherapies.

FY 2021 ECI Award Application Data

RFA Mechanism	# Applications Submitted	Requested Funding
Early Clinical Investigator Award	11	\$16,426,401



UAC –Recommendations

- “Stay the Course” – Maintain Outstanding Programs
 - Scholars Program
 - Infrastructure Program
 - Balanced portfolio of “Best Science” Programs (Targeted and Un-targeted Investigator Initiated Research Awards)
- Adjust to New Opportunities
 - Build strength in cancer research across the State
 - Strengthen to support clinical research through investigator-based programs
 - Promote translation of research to commercialization
- Prioritize – Young Investigators and Innovation

10-25





Andrew L. Strong

Andrew Strong is a Texas-based business advisor and lawyer with deep experience helping start-up through publicly traded biotech companies. He has experience as a biotech founder, general counsel of large university system and lawyer advising on corporate and securities, mergers & acquisitions, private and public financing, university licensing, executive compensation and regulatory matters.

Andrew's clients include public- and private-sector entities in the emerging technology and life sciences industries and public and private academic institutions. Andrew previously served as the General Counsel and Compliance Officer for the Texas A&M University System where he was responsible for, among other things, business transactions, technology commercialization, research compliance, real estate and litigation for the System's 11 public universities, 7 state agencies and health science center.

Andrew was the Founding President and CEO of a start-up biotech company (Kalon Biotherapeutics) which was formed by the Texas A&M System in 2011 and was integral to the multi-billion dollar award from the Biomedical Advanced Research & Development Authority (BARDA) in 2012. Over the course of three years, Andrew successfully grew Kalon to over 100 employees and secured significant partnerships with MD Anderson Cancer Center and the pharmaceutical company GlaxoSmithKline. He then successfully ran a process to secure a strategic exit for Kalon that resulted in the sale of the company to Fujifilm Diosynth Biotechnologies in December 2014, which now employs over 600 in Bryan/College Station.

Following the sale of Kalon in 2015, Andrew set his focus on helping grow the Texas biotechnology industry and now represents over 30 private and public biotech companies, a number of which are CPRIT-funded companies. He is also recently founded K2 Biolabs in Houston, a drug development accelerator for biotech companies and provider of pre-clinical research services.



Michele Park

Michele Park, PhD, served as a Partner for the life sciences venture capital firm Clarus (now Blackstone Life Sciences) and led the Clarus Cancer Fund, a novel investment model aimed at generating financial returns and amplifying scientific and medical impacts by donating a portion of the Cancer Fund's returns to advance basic science research in cancer.

Dr. Park joined Clarus in 2006 with six years of sell-side equity research experience covering the biotechnology sector. From 2002-2005, Dr. Park was a research analyst at Credit Suisse First Boston, where she covered biotechnology stocks as a member of the firm's US biotechnology team. Before joining CSFB, Dr. Park was a biotechnology research analyst at US Bancorp Piper Jaffray. Dr. Park received a PhD in Molecular Biology from Weill Cornell University's Graduate School of Biomedical Sciences, completing her PhD dissertation at Memorial Sloan-Kettering Cancer Center, and a BA in Molecular Biology from Princeton University.

Michele is a member of Curesearch Children Cancer's Catapult Advisory Council and represented Clarus on the Board of Directors of [Lumos](#) and as a Board observer of [SFJ](#). Previous Board seats have included [Sientra \(NASDAQ:SIEN\)](#) and Board observer roles at [Achillion](#) and [Comentis](#). Michele is also a member of the Private Equity Women Investor Network (PEWIN), a member of the Council of Korean Americans (CKA), and a Board Trustee for the American Friends of the Royal Philharmonic Orchestra (AFRPO).



CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

CPRIT Product Development Research Advisory Committee Recommendations

Co-Chairs: Andrew Strong, JD
Michele Park, PhD

10-28

Product Development Advisory Committee (PDAC)

Andrew Strong, JD, Partner, Pillsbury Winthrop Shaw Pittman LLP*

Michele Park, PhD, Former Partner, Clarus Funds

David Arthur, CEO, Salarius Pharmaceuticals*

Paul Lammers, MD, CEO, Triumvira Immunologics, Inc.*

David Lowe, PhD, Co-Founder, Aeglea Biotherapeutics; MDir, AllosteRx Capital*

Dennis McWilliams, Venture Partner, Sante Ventures*

Tracy Saxton, PhD, CEO, Lengo Therapeutics; Adviser, Frazier Healthcare Partners

Greg Stein, MD, CEO, Curtana Pharmaceuticals*

Matt Winkler, PhD, Chairman, Asuragen, Inc.*

Clair Aldridge, PhD, former AVP for Commercialization, UTSW; Pegasus Park

Bruce Butler, PhD, VP, Research and Technology, Director, OTM, UTHSC at Houston

Julie Goonewardene, AVP for Innovation and Strategic Investment, UT System

Greg Hartman, COO, TAMU Health Science Center, Vice Chancellor TAMU System

Jonathan MacQuitty, PhD, Venture Partner, Lightspeed Venture Partners

Emma Schwartz, President, Medical Center of the Americas Foundation

Ann Tanabe, CEO, BioHouston, Inc.

10-29



CPRIT Grant Award Data

1,585 Awards Totaling \$2.67 Billion

Academic Research

1,292 awards, \$1.91 Billion

Product Development

49 awards, \$477.4 Million

Prevention

244 awards, \$277.7 Million

- 42 companies funded, including 14 relocation companies
- 27 TXCO, 14 RELCO, 8 SEED awards
- 6 companies with multiple awards
- 20 awardee companies conducting active clinical trials

- \$3.66 billion direct follow-on funding raised by companies (> 7 to 1)
- 1100+ jobs created in Texas
- Products launched
 - Visualase MRI-Guided Laser Ablation** (acquired by Medtronic)
 - Multiple NGS products** developed/launched by Asuragen
 - OncologyMAP** developed by RBM (acquired by Myriad)



CPRIT Product Development Research

CPRIT has dramatically contributed to the growth of the Texas biotech ecosystem.



Product Development Research Funding Metrics

Cycle	All 3 Programs	TXCO and RELCO Awards				Seed Awards			
	Total Apps	Apps	In-Person	Diligence	PDRC Rec'd	Apps	In-Person	Diligence	PDRC Rec'd
16.1	25	25	12	5	2				
16.2	32	32	13	7	2				
17.1	19	19	8	3	0				
17.2	20	20	6	2	1				
18.1	18	18	4	2	0				
18.2	20	20	10	6	3				
19.1	38	13	6	6	2	25	11	4	3
19.2	27	13	6	2	2	14	5	2	1
20.1	40	24	9	3	1	16	7	4	4
20.2	28	19	8	4	2	9	0	0	0
Totals	267	203	82	40	15	64	23	10	8
% of Apps		-	40%	20%	7%	-	36%	16%	13%



Overarching PDAC Recommendations

Recommendation #1:

Increase the # of Product Development awards made annually

- Goal is to allocate ~30% of annual CPRIT budget to Product Development Research (\$60 to \$70 million/year)
- CPRIT has never achieved that goal in its existence

Recommendation #2:

Implement New Funding Opportunities/RFAs

- Focus on Starting up/Spinning out NewCos
- Regional or Cross Platform Acceleration Programs

10-33



PDAC Pre-Award Recommendations

Recommendation #1:

Enhance current RFAs to improve guidance for applicants

- Provide more detailed guidance on what constitutes a successful application
- Highlight key factors distinguishing SEED vs TXCO/RELCO
- Highlight how key review factors (SEED vs TXCO/RELCO) may differ for different categories (therapeutic, diagnostics, devices, tools, etc.)

Recommendation #2:

Improve and increase reviewer guidance

- Particularly for SEED applications
- Consider a process where an industry-specific mentor would work with an applicant for guidance and advisement during application process

10-34



PDAC Post-Award Recommendations

Recommendation #1:

Streamline grantee annual reporting/review process with PDRC

- Allow grantees to present annual progress reports to PDRC via video teleconference and promoting real-time Q&A
- Assign member of PDRC to each grantee to “check in” periodically

Recommendation #2:

Allow for reasonable flexibility in a grantee’s project implementation and conduct “mini reviews” with PDRC members to allow for mid-course corrections if necessary

10-36



PDAC Post-Award Recommendations

Recommendation #3:

CPRIT should be looking for ways to help the companies be successful

- Support grantee 'Demo Day' with investors, perhaps in conjunction with Texas Life Science Venture Forum
- Support and fund formation of best practices/EIR type services and outreach for CPRIT-funded companies

Recommendation #4:

Highlight metrics that matter, including # clinical trials and # patients enrolled

10-37





Navkiran K. Shokar, MA, MD, MPH is professor and chair of the Department of Population Health and Associate Dean for Community Affairs at Dell Medical School at the University of Texas at Austin. She was born and raised in England where she received her Master of Arts degree from the University of Cambridge and her medical degree from the University of Oxford Medical School. She was previously at UTMB Galveston and Texas Tech University Health Sciences Center El Paso. Dr. Shokar's research focuses on multilevel clinic and community-based interventions that bridge the divide between public health, the community and the health care system in order to address cancer health disparities among racial/ethnic minorities and vulnerable populations. Her work incorporates theory-based health promotion methods and culturally tailoring to maximize intervention effectiveness.



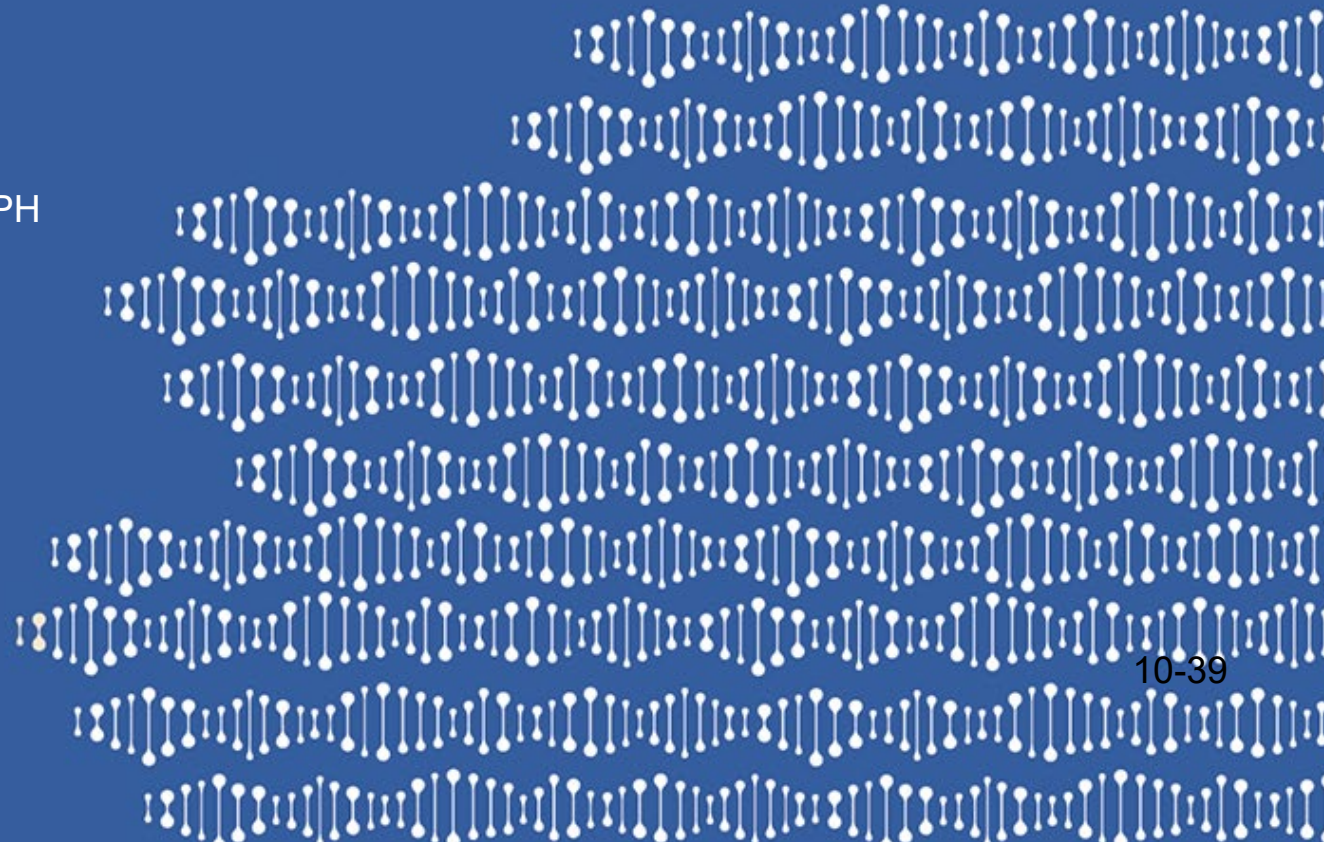
CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

Prevention Advisory Committee

May 19th 2021

Presented By:

Navkiran Shokar, MA MD MPH



Prevention Advisory Committee

- First Convened March 2021
- Current roster
 - Navkiran Shokar, MD, MPH; Chair
 - Keith Argenbright, MD
 - Abbey Berenson, MD
 - Roxana Cruz, MD
 - David Lakey, MD
 - Mike Pignone, MD, MPH
 - Ken Ramos, MD, PhD
 - Suncerria Tullis, MBA

10-40

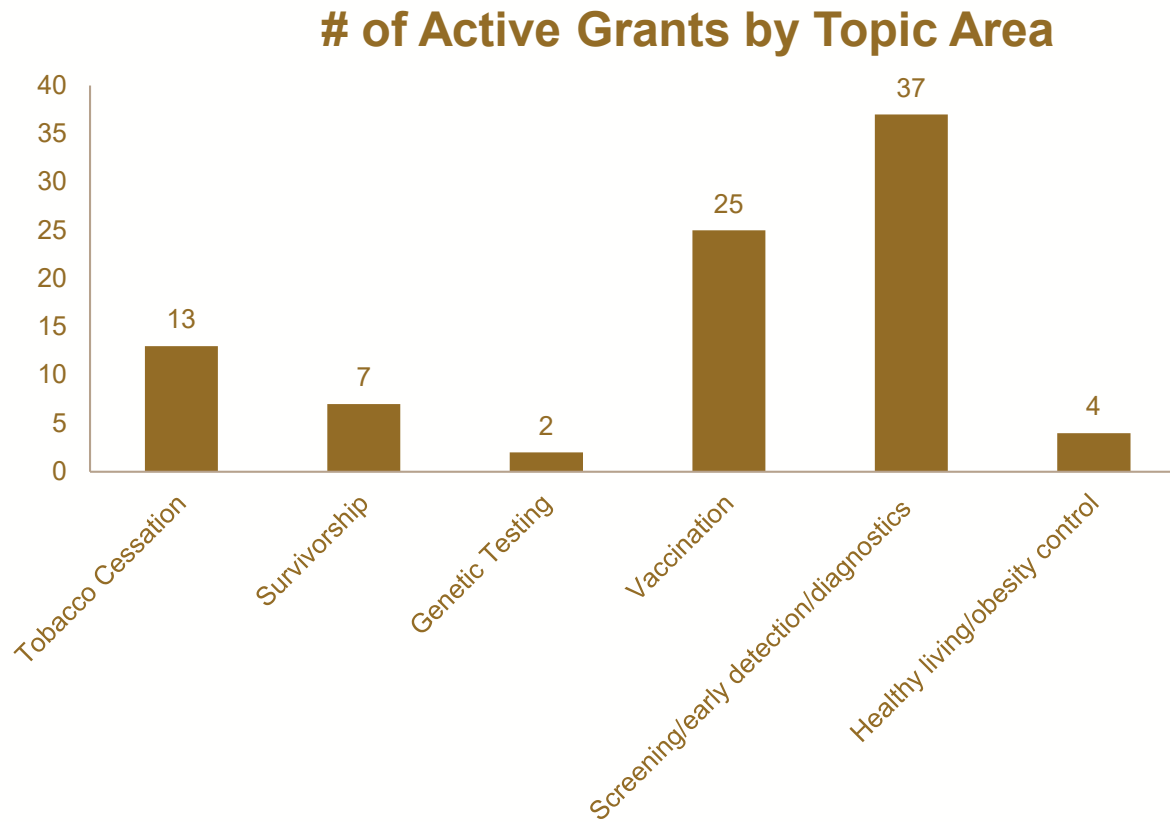


FY2020 Applications and Awards

Cycle	# Applications	\$ Requested	# Awards	Funded Amount
20.1	33	\$ 38,340,125	10	\$ 13,507,769
20.2	18	\$ 24,183,674	8	\$ 14,063,633
TOTAL	51	\$ 62,523,799	18	\$ 27,751,402



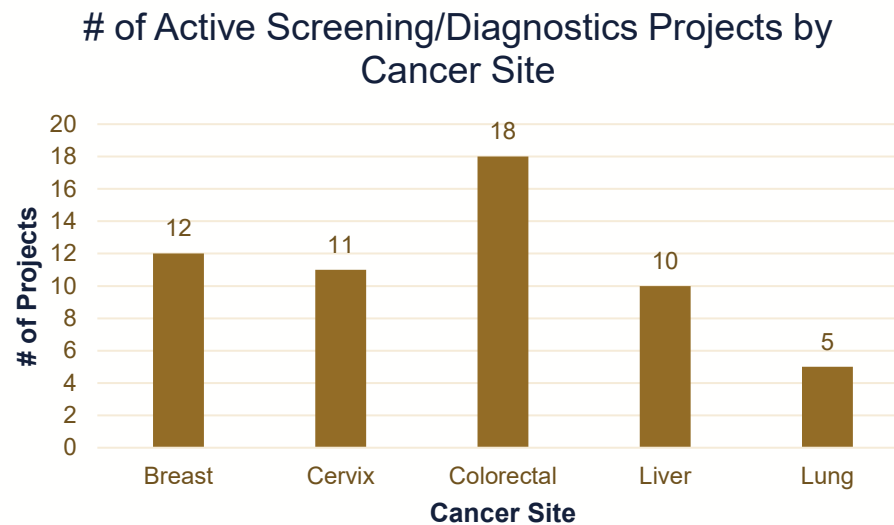
68 Active Prevention Projects



Note: Some projects offer multiple clinical services



Active Screening/Diagnostics Projects



Note: Some projects screen for multiple cancer sites



Cancer Prevention in Texas in 2020-2021

COVID 19:

- Impact on community and patients
 - Impact on clinical service providers
 - Impact on grantees & projects
-
- Increased the need in the community
 - Created a backlog of services
 - Required new approaches

10-45



Progress on 2020 Recommendations

- Released new evaluation RFA to synthesize progress and inform planning for next decade.
- Extended **duration** and **amount** of funding for established continuation grants from 3 to 5 years.
- Held planning meetings for a statewide initiative that would address and integrate three of last year's recommendations
 - Statewide coordinated cancer prevention and control infrastructure
 - Regional cancer prevention hub /center approach
 - Streamlined program to enhance access to funding for small organizations

10-46



Future Directions

- Continue to develop statewide initiative and RFA
- Continue work on seamlessly integrating prevention and academic program side
- Capacity building for smaller organizations and newer academic centers
- Collate and share experiences and best practices from the covid pandemic

10-47





Richard Gorlick, M.D.

Dr. Richard Gorlick is Division Head and Department Chair of Pediatrics, Department Chair ad interim of Sarcoma Medical Oncology in the Division of Cancer Medicine at the MD Anderson Cancer Center, and H. Grant Taylor, M.D., W. W. Sutow, M.D. and Margaret P. Sullivan, M.D. Distinguished Chair in Pediatrics. Dr. Gorlick received his medical degree from Downstate Medical School. He trained at New York-Presbyterian and Memorial Sloan-Kettering Cancer Center, where he began his sarcoma research laboratory and clinical practice. His laboratory is the founding Bone Tumor Resource Laboratory for the Children's Oncology Group. His molecular pharmacology laboratory is completely focused on osteosarcoma. His laboratory is a member of the NCI-funded Pediatric Preclinical Testing Consortium. Dr. Gorlick is involved in clinical trials, in part, as past chair of the Bone Tumor Disease Committee for COG. He is a past president of the Connective Tissue Oncology Society. Dr. Gorlick has published more than 296 peer-reviewed papers, reviews and book chapters.



CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

MEMORANDUM

TO: OVERSIGHT COMMITTEE MEMBERS

FROM: KRISTEN PAULING DOYLE, DEPUTY EXECUTIVE OFFICER &
GENERAL COUNSEL
CAMERON L. ECKEL, ASSISTANT GENERAL COUNSEL

SUBJECT: CHAPTERS 702 AND 703 RULE CHANGES PROPOSED FOR FINAL
ADOPTION

DATE: MAY 10, 2021

Summary and Recommendation

The Board Governance Subcommittee recommends that the Oversight Committee adopt the proposed administrative rule changes to Chapters 702 and 703 as originally considered at the February 17, 2021, meeting. Once the Oversight Committee approves the final orders adopting the rule changes, CPRIT will submit the amendments to the Secretary of State and the changes will be effective 20 days later.

Discussion

State law requires an agency to set policy using a rulemaking process, which includes an opportunity for public comment on proposed rules and rule changes before the agency formally adopts the policy. CPRIT published the proposed amendments in the March 5, 2021, edition of the *Texas Register*. CPRIT received one comment in support of the proposed rule amendment to Chapter 702.

The rule amendment to § 702.19(b) provides a limited exception to the general communication prohibition between a grant applicant and a peer reviewer. (CPRIT's administrative rules refer to peer reviewers by the term used in the statute – a "Scientific Research and Prevention Programs Committee" member.) The exception allows a peer reviewer assigned by the Product Development Review Council (PDRC) Chairperson to participate in the interview with the applicant during the business and operations and/or intellectual property due diligence review. Assigning a peer reviewer to directly interact with a grant applicant during this stage of review helps to ensure that the PDRC has all the information it needs to evaluate a grant application. All grant applicants that reach due diligence review will be subject to the same process.

The rule change to § 703.10(c)(3) requires a grantee to include CPRIT grant identification numbers in the acknowledgement of CPRIT funding. CPRIT requires all grant recipients to acknowledge CPRIT funding in any publication.

The Board Governance Subcommittee met on May 6 to discuss adoption of the proposed rule changes to §§ 702.19(b) and 703.10(c)(3) with CPRIT staff. The subcommittee voted to recommend that the Oversight Committee approve adoption of the rule changes.

Next Steps

After the Oversight Committee adopts the proposed rule changes, CPRIT will submit the final order to the Secretary of State. The rule changes become effective 20 days after the date CPRIT files the order with the Secretary of State.

The Cancer Prevention and Research Institute of Texas (“CPRIT” or “the Institute”) adopts the amendment to 25 Tex. Admin. Code § 702.19(b) without changes to the proposed amendment as published in the March 5, 2021, issue of the *Texas Register* (46 TexReg 1457); therefore, the rule will not be republished. The amendment relates to an exception to the general communication prohibition between a grant applicant and a member of the Scientific Research and Prevention Programs Committee (SRPP) regarding the substance of a pending application.

Reasoned Justification

The amendment to § 702.19(b) allows an SRPP member, assigned by the Product Development Review Council (PDRC) Chairperson, to participate in interviewing a grant applicant as part of the business operations and management due diligence and/or intellectual property review process conducted by CPRIT contractors. The assigned SRPP member will relay information to the full PDRC to assist in their grant application review.

Summary of Public Comments and Staff Recommendation

CPRIT received one public comment from Mr. David Shubert, President of Magnolia Tejas Corporation, in favor of adoption. CPRIT staff recommends proceeding with adoption of the amendment to § 702.19(b).

Statutory Authority

CPRIT adopts the rule change under the authority of the Texas Health and Safety Code Annotated, § 102.108, which provides the Institute with broad rule-making authority to administer the chapter, including rules for awarding grants.

Certification

The Institute hereby certifies that Kristen Pauling Doyle, Deputy Executive Officer and General Counsel, reviewed the adoption of the rule and found it to be a valid exercise of the agency’s legal authority.

To be filed with the Office of Secretary of State on May 21, 2021.

<rule>

§702.19. Restriction on Communication Regarding Pending Grant Application.

(a) Communication regarding the substance of a pending Grant Application between the Grant Applicant and an Oversight Committee Member, a Program Integration Committee Member, or a Scientific Research and Prevention Programs Committee Member is prohibited.

(b) The prohibition on communication begins on the first day that Grant Applications for the Grant Mechanism are accepted by the Institute and extends until the Grant Applicant receives notice regarding a final decision on the Grant Application.

(1) The prohibition on communication does not apply to the time period when pre-applications or letters of interest are accepted.

(2) In special circumstances, an Oversight Committee Member or a Program Integration Committee Member may respond to a question or request for more information from a Grant Applicant so long as the response is made available to all Grant Applicants.

(3) The prohibition does not apply to a Scientific Research and Prevention Programs Committee Member who is assigned by the Product Development Review Council chairperson to participate in the business operations and management due diligence review and intellectual property review as described in Chapter 703 of this title (relating to Grants for Cancer Prevention and Research). A Scientific Research and Prevention Programs Committee Member, on behalf of the Product Development Review Council, may participate in the due diligence review process and ask clarifying questions of a Grant Applicant to gain substantive knowledge, which the Product Development Review Council will use in the review of the Grant Application.

(A) Each Grant Application recommended to the due diligence stage of review will be subject to the same review and participation by a Scientific Research and Prevention Programs Committee Member as described in paragraph (3) of this subsection.

(B) The Institute will maintain documentation of the Scientific Research and Prevention Programs Committee Members assigned to participate in due diligence review.

(c) Intentional, serious, or frequent violations of this rule may result in the disqualification of the Grant Applicant from further consideration for a Grant Award.

(d) This rule is not intended to prohibit open dialogue between the public and the Chief Executive Officer, a Program Integration Committee Member or a member of the Oversight Committee regarding the general status or nature of pending Grant Applications.

(e) The Chief Executive Officer may grant a waiver from the general prohibition on communication upon finding that the waiver is in the interest of promoting the objectives of the Institute and is not intended to give one or more Grant Applicants an unfair advantage. The waiver shall be provided to the Oversight Committee in writing at the time it is granted and state the reasons for the granting the waiver. The waiver shall be included as part of the public information supporting the Chief Executive Officer's affidavit(s) for Grant Award recommendations in the Grant Review Cycle(s) corresponding to the waiver.

(f) A Program Integration Committee Member shall not communicate individually with one or more Oversight Committee Members about a Grant Award recommendation for a Grant Application in a pending Grant Review Cycle until such time that the Program Integration Committee has submitted the list of Grant Award Recommendations to the Oversight Committee and the Chief Executive Officer has submitted the written affidavit required by Chapter 703, §703.7 of this title (relating to Program Integration Committee Funding Recommendation). Nothing herein shall prohibit the Chief Executive Officer or a Program Integration Committee Member from responding to an individual Oversight Committee Member's question or request

for more information so long as the response is made available to all Oversight Committee Members.

The Cancer Prevention and Research Institute of Texas (“CPRIT” or “the Institute”) adopts the amendment to 25 Tex. Admin. Code § 703.10(c)(3) without changes to the proposed amendment as published in the March 5, 2021, issue of the *Texas Register* (46 TexReg 1459); therefore, the rule will not be republished. In addition to correcting grammar and punctuation for clarity, the amendment requires a grant recipient to include applicable CPRIT grant identification numbers when acknowledging CPRIT funding in publications.

Reasoned Justification

CPRIT requires grant recipients to acknowledge Institute funding when publishing the research results. The amendment to § 703.10(c)(3) clarifies that, beginning September 1, 2021, acknowledgments must include applicable grant identification numbers. Including grant identification numbers helps the Institute track outcomes of grant awards. The Institute has also made non-substantive grammar and punctuation corrections throughout § 703.10.

Summary of Public Comments and Staff Recommendation

CPRIT did not receive any public comments regarding the amendment to § 703.10(c)(3); CPRIT staff recommends proceeding with adoption.

Statutory Authority

CPRIT adopts the rule change under the authority of the Texas Health and Safety Code Annotated, § 102.108, which provides the Institute with broad rule-making authority to administer the chapter, including rules for awarding grants.

Certification

The Institute hereby certifies that Kristen Pauling Doyle, Deputy Executive Officer and General Counsel, reviewed the adoption of the rule change and found it to be a valid exercise of the agency’s legal authority.

To be filed with the Office of Secretary of State on May 21, 2021.

<rule>

§703.10. Awarding Grants by Contract.

- (a) The Oversight Committee shall negotiate on behalf of the state regarding the awarding of grant funds and enter into a written contract with the Grant Recipient.
- (b) The Oversight Committee may delegate Grant Contract negotiation duties to the Chief Executive Officer and the General Counsel for the Institute. The Chief Executive Officer may enter into a written contract with the Grant Recipient on behalf of the Oversight Committee.
- (c) The Grant Contract shall include the following provisions:

(1) If any portion of the Grant Contract has been approved by the Oversight Committee to be used to build a capital improvement, the Grant Contract shall specify that:

(A) The state retains a lien or other interest in the capital improvement in proportion to the percentage of the Grant Award amount used to pay for the capital improvement; and

(B) If the capital improvement is sold, then the Grant Recipient agrees to repay to the state the Grant Award used to pay for the capital improvement, with interest, and share with the state a proportionate amount of any profit realized from the sale;

(2) Terms relating to Intellectual Property Rights and the sharing with the Institute of revenues generated by the sale, license, or other conveyance of such Project Results consistent with the standards established by this chapter;

(3) Terms relating to publication of materials created with Grant Award funds or related to the Cancer Research or Cancer Prevention project that is the subject of the Grant Award, including an acknowledgement of Institute funding and copyright ownership, if applicable: [§]

(A) Acknowledgment of Institute funding must include the grant number of every Institute-funded grant contributing to the work memorialized in the publication; and

(B) Subparagraph (A) of this paragraph is effective beginning September 1, 2021;

(4) Repayment terms, including interest rates, to be enforced if the Grant Recipient has not used Grant Award funds for the purposes for which the Grant Award was intended;

(5) A statement that the Institute does not assume responsibility for the conduct of the Cancer Research or Cancer Prevention project, and that the conduct of the project and activities of all investigators are under the scope and direction of the Grant Recipient;

(6) A statement that the Cancer Research or Cancer Prevention project is conducted with full consideration for the ethical and medical implications of the project and that the project will comply with all federal and state laws regarding the conduct of the Cancer Research or Prevention project;

(7) Terms related to the Standards established by the Oversight Committee in Chapter 701 of this title (relating to Policies and Procedures) to ensure that Grant Recipients, to the extent reasonably possible, demonstrate good faith effort to purchase goods and services for the Grant Award project from suppliers in this state and from historically underutilized businesses as defined by Chapter 2161, Texas Government Code, and any other state law;

(8) An agreement by the Grant Recipient to submit to regular inspection reviews of the Grant Award project by Institute staff during normal business hours and upon reasonable notice to ensure compliance with the terms of the Grant Contract and continued merit of the project;

(9) An agreement by the Grant Recipient to submit Grant Progress Reports to the Institute on a schedule specified by the Grant Contract that ~~includes~~ ~~[include]~~ information on a grant-by-grant basis quantifying the amount of additional research funding, if any, secured as a result of Institute funding;

(10) An agreement that, to the extent possible, the Grant Recipient will evaluate whether any new or expanded preclinical testing, clinical trials, Product Development, or manufacturing of any real or intellectual property resulting from the award can be conducted in this state, including the establishment of facilities to meet this purpose;

(11) An agreement that the Grant Recipient will abide by the Uniform Grant Management Standards (UGMS) adopted by the Governor's Office, if applicable, unless one or more standards conflicts with a provision of the Grant Contract, Chapter 102, Texas Health and Safety Code, or the Institute's administrative rules. Such interpretation of the Institute rules and UGMS shall be made by the Institute;

(12) An agreement that the Grant Recipient is under a continuing obligation to notify the Institute of any adverse conditions that materially impact milestones and objectives included in the Grant Contract;

(13) An agreement that the design, conduct, and reporting of the Cancer Research or Prevention project will not be biased by conflicting financial interest of the Grant Recipient or any individuals associated with the Grant Award. This duty is fulfilled by certifying that an appropriate written, enforced Conflict of Interest policy governs the Grant Recipient; [-]

(14) An agreement regarding the amount, schedule, and requirements for payment of Grant Award funds, if such advance payments are approved by the Oversight Committee in accordance with this chapter. Notwithstanding the foregoing, the Institute may require that up to ten percent of the final tranche of funds approved for the Grant Award must be expended on a reimbursement basis. Such reimbursement payment shall not be made until close out documents described in this section and required by the Grant Contract have been submitted and approved by the Institute;

(15) An agreement to provide quarterly Financial Status Reports and supporting documentation for expenses submitted for reimbursement or, if appropriate, to demonstrate how advanced funds were expended;

(16) A statement certifying that, as of June 14, 2013, the Grant Recipient has not made and will not make a contribution, during the term of the Grant Contract, to the Institute or to any foundation established specifically to support the Institute;

(17) A statement specifying the agreed effective date of the Grant Contract and the period in which the Grant Award funds must be spent. If the effective date specified in the Grant Contract is different from the date the Grant Contract is signed by both parties, then the effective date shall control;

(18) A statement providing for reimbursement with Grant Award funds of expenses made prior to the effective date of the Grant Contract at the discretion of the Institute. Pre-contract reimbursement shall be made only in the event that:

(A) The expenses are allowable pursuant to the terms of the Grant Contract;

(B) The request is made in writing by the Grant Recipient and approved by the Chief Executive Officer; and

(C) The expenses to be reimbursed were incurred on or after the date the Grant Award recommendation was approved by the Oversight Committee; [-]

(19) Requirements for closing out the Grant Contract at the termination date, including the submission of a Financial Status Report, a final Grant Progress Report, an [a] equipment inventory, a HUB and Texas Business report, a revenue sharing form, a single audit determination report form and a list of contractual terms that extend beyond the termination date;

(20) A certification of dedicated Matching Funds equal to one-half of the amount of the Research Grant Award that includes the name of the Research Grant Award to which the matching funds are to be dedicated, as specified in Section §703.11 of this chapter (relating to Requirement to Demonstrate Available Funds for Cancer Research Grants);

(21) The project deliverables as described by the Grant Application and stated in the Scope of Work for the Grant Contract reflecting modifications, if any, approved during the Peer Review process or during Grant Contract negotiation; [and]

(22) An agreement that the Grant Recipient shall notify the Institute and seek approval for a change in effort for any of the Senior Members or Key Personnel of the research or prevention team listed on the Grant Application, including any proposed temporary leave of absence of a Principal Investigator, Program Director, or Company Representative; [-]

(23) An agreement that the Grant Recipient is legally responsible for the integrity of the fiscal and programmatic management of the organization; and -

(24) An agreement that the Grant Recipient is responsible for the actions of its employees and other research collaborators, including third parties, involved in the project. The Grant Recipient is responsible for enforcing its standards of conduct, taking appropriate action on individual infractions, and, in the case of financial conflict of interest, informing the Institute if the infraction is related to a Grant Award.

(d) The Grant Recipient's failure to comply with the terms and conditions of the Grant Contract may result in termination of the Grant Contract, pursuant to the process prescribed in the Grant Contract, and trigger repayment of the Grant Award funds.



CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

MEMORANDUM

TO: OVERSIGHT COMMITTEE MEMBERS

FROM: KRISTEN PAULING DOYLE, DEPUTY EXECUTIVE OFFICER &
GENERAL COUNSEL
CAMERON L. ECKEL, ASSISTANT GENERAL COUNSEL

SUBJECT: CHAPTER 703 - PROPOSED RULE CHANGE

DATE: MAY 10, 2021

Summary and Recommendation

The Board Governance Subcommittee met on May 6 and recommends that the Oversight Committee approve one proposed administrative rule change to Chapter 703 for publication in the *Texas Register*. Publication of the anticipated rule change in the *Texas Register* is the first step in the agency rulemaking process. CPRIT Staff will bring back the proposed rule and any public comments to the Oversight Committee in August for final approval.

Discussion

CPRIT's administrative rules set policy guiding CPRIT's grant review and grant contracting processes as well as managing other requirements of Texas Health and Safety Code Chapter 102. State law requires agencies to use a rulemaking process, which includes an opportunity for the public to comment on the rule changes before the agency adopts the final policy.

The Board Governance Subcommittee met on May 6 to discuss the proposed rule change to § 703.26 with CPRIT staff. The subcommittee voted to recommend that the Oversight Committee approve the following suggested rule change for publication.

The proposed amendment to Section 703.26 harmonizes CPRIT's administrative rules with statutory changes made to Texas Health and Safety Code in 2019. With the goal of increasing the number of Texans participating in cancer clinical trials, the 86th Texas Legislature adopted legislation in 2019 creating the Cancer Clinical Trial Participation Program in [Texas Health and Safety Code Chapter 50](#). The program's statutory purpose is to "to provide reimbursement to subjects for ancillary costs associated with participation in a cancer clinical trial, including costs for: travel; lodging; parking and tolls; and other costs considered appropriate." The legislature also amended CPRIT's statute (Texas Health and Safety Code § 102.203(b)) to allow reimbursement for certain clinical trial participant costs, including transportation, lodging, and costs reimbursed under a program established pursuant to Chapter 50.

In response to these statutory changes, CPRIT released a new Request for Applications (RFA) for the [Texas Clinical Trials Participation Program Award](#) in August 2020. CPRIT will announce the inaugural clinical trial participation grants at its August 18, 2021, Oversight Committee meeting.

Next Steps

Once approved by the Oversight Committee, CPRIT will publish the proposed rule change in the *Texas Register*. The publication date begins the 30-day period for soliciting comment from interested members of the public. CPRIT will also post the proposed rule changes on our website and announce the opportunity for public comment via CPRIT's electronic list serve. CPRIT legal staff will summarize any comments received from the public for the Oversight Committee's consideration when approving the final rule changes in August.

The Cancer Prevention and Research Institute of Texas (“CPRIT” or “the Institute”) proposes an amendment to 25 Tex. Admin. Code § 703.26 clarifying that CPRIT may reimburse certain expenses incurred by participants in a cancer clinical trial pursuant to the authority provided by Texas Health and Safety Code Annotated, § 102.203(b).

Background and Justification

The 86th Legislature adopted H.B. 3147, creating Texas Health and Safety Code Annotated, Chapter 50 “Cancer Clinical Trial Participation Program.” The legislature also amended CPRIT’s statute to authorize reimbursement for costs of participation incurred by cancer clinical trial participants, including transportation, lodging, and costs reimbursed under a program established pursuant to Chapter 50. The proposed amendment to § 703.26 makes the administrative rule consistent with the statutory changes regarding reimbursement for expenses associated with participating in a cancer clinical trial.

Fiscal Note

Kristen Pauling Doyle, Deputy Executive Officer and General Counsel for the Cancer Prevention and Research Institute of Texas, has determined that for the first five-year period the rule change is in effect, there will be no foreseeable implications relating to costs or revenues for state or local government due to enforcing or administering the rule.

Public Benefit and Costs

Ms. Doyle has determined that for each year of the first five years the rule change is in effect the public benefit anticipated due to enforcing the rule will be clarification regarding the information the grant recipient must provide when acknowledging Institute funding in publications.

Small Business, Micro-Business, and Rural Communities Impact Analysis

Ms. Doyle has determined that the rule change will not affect small businesses, micro businesses, or rural communities.

Government Growth Impact Statement

The Institute, in accordance with 34 Texas Administrative Code §11.1, has determined that during the first five years that the proposed rule change will be in effect:

- (1) the proposed rule change will not create or eliminate a government program;
- (2) implementation of the proposed rule change will not affect the number of employee positions;
- (3) implementation of the proposed rule change will not require an increase or decrease in future legislative appropriations;
- (4) the proposed rule change will not affect fees paid to the agency;
- (5) the proposed rule change will not create new rule;

- (6) the proposed rule change will not expand existing rule;
- (7) the proposed rule change will not change the number of individuals subject to the rule; and
- (8) The rule change is unlikely to have an impact on the state's economy. Although the change is likely to have neutral impact on the state's economy, the Institute lacks enough data to predict the impact with certainty.

Submit written comments on the proposed rule change to Ms. Kristen Pauling Doyle, General Counsel, Cancer Prevention and Research Institute of Texas, P. O. Box 12097, Austin, Texas 78711, no later than July 5, 2021. The Institute asks parties filing comments to indicate whether they support the rule revision proposed by the Institute and, if a party requests a change, to provide specific text to include in the rule. Parties may submit comments electronically to kdoyle@cprit.texas.gov or by facsimile transmission to 512/475-2563.

Statutory Authority

The Institute proposes the rule change under the authority of the Texas Health and Safety Code Annotated, § 102.108, which provides the Institute with broad rule-making authority to administer the chapter. Ms. Doyle has reviewed the proposed amendment and certifies the proposal to be within the Institute's authority to adopt.

There is no other statute, article, or code affected by these rules.

<rule>

§703.26. Allowable Costs.

(a) A cost is an Allowable Cost and may be charged to the Grant Award if it is reasonable, allocable, and adequately documented.

(1) A cost is reasonable if the cost does not exceed that which would be incurred by a prudent individual or organization under the circumstances prevailing at the time the decision was made to incur the cost; and is necessary for the performance of the Grant Award defined in the Scope of Work in the Grant Contract.

(2) A cost is allocable if the cost:

(A) Benefits the Grant Award either directly or indirectly, subject to Indirect Cost limits stated in the Grant Contract;

(B) Is assigned the Grant Award in accordance with the relative benefit received;

(C) Is allowed or not prohibited by state laws, administrative rules, contractual terms, or applicable regulations;

(D) Is not included as a cost or used to meet Matching Fund requirements for any other Grant Award in either the current or a prior period; and

(E) Conforms to any limitations or exclusions set forth in the applicable cost principles, administrative rules, state laws, and terms of the Grant Contract.

(3) A cost is adequately documented if the cost is supported by the organization's accounting records and documented consistent with §703.24 of this title (relating to Financial Status Reports).

(b) Grant Award funds must be used for Allowable Costs as provided by the terms of the Grant Contract, Chapter 102, Texas Health and Safety Code, the Institute's administrative rules, and the Uniform Grant Management Standards (UGMS) adopted by the Comptroller's Office. If guidance from the Uniform Grant Management Standards on a particular issue conflicts with a specific provision of the Grant Contract, Chapter 102, Texas Health and Safety Code or the Institute's administrative rules, then the Grant Contract, statute, or Institute administrative rule shall prevail.

(c) An otherwise Allowable Cost will not be eligible for reimbursement if the Grant Recipient incurred the expense outside of the Grant Contract term, unless the Grant Recipient has received written approval from the Institute's Chief Executive Officer to receive reimbursement for expenses incurred prior to the effective date of the Grant Contract.

(d) An otherwise Allowable Cost will not be eligible for reimbursement if the benefit from the cost of goods or services charged to the Grant Award is not realized within the applicable term of the Grant Award. The Grant Award should not be charged for the cost of goods or services that benefit another Grant Award or benefit a period prior to the Grant Contract effective date or after the termination of the Grant Contract.

(e) Grant Award funds shall not be used to reimburse unallowable expenses, including, but not limited to:

(1) Bad debt, such as losses arising from uncollectible accounts and other claims and related costs.

(2) Contributions to a contingency reserve or any similar provision for unforeseen events.

(3) Contributions and donations made to any individual or organization.

(4) Costs of entertainment, amusements, social activities, and incidental costs relating thereto, including tickets to shows or sports events, meals, alcoholic beverages, lodging, rentals, transportation and gratuities.

(5) Costs relating to food and beverage items, unless the food item is related to the issue studied by the project that is the subject of the Grant Award.

(6) Fines, penalties, or other costs resulting from violations of or failure to comply with federal, state, local or Indian tribal laws and regulations.

- (7) An honorary gift or a gratuitous payment.
- (8) Interest and other financial costs related to borrowing and the cost of financing.
- (9) Legislative expenses such as salaries and other expenses associated with lobbying the state or federal legislature or similar local governmental bodies, whether incurred for purposes of legislation or executive direction.
- (10) Liability insurance coverage.
- (11) Benefit replacement pay or legislatively-mandated pay increases for eligible general revenue-funded state employees at Grant Recipient state agencies or universities.
- (12) Professional association fees or dues for an individual employed by the Grant Recipient. Professional association fees or dues for the Grant Recipient's membership in business, technical, and professional organizations may be allowed, with prior approval from the Institute, if:
 - (A) the professional association is not involved in lobbying efforts; and
 - (B) the Grant Recipient demonstrates how membership in the professional association benefits the Grant Award project(s).
- (13) Promotional items and costs relating to items such as T-shirts, coffee mugs, buttons, pencils, and candy that advertise or promote the project or Grant Recipient.
- (14) Fees for visa services.
- (15) Payments to a subcontractor if the subcontractor working on a Grant Award project employs an individual who is a Relative of the Principal Investigator, Program Director, Company Representative, Authorized Signing Official, or any person designated as Key Personnel for the same Grant Award project (collectively referred to as "affected Relative"), and:
 - (A) the Grant Recipient will be paying the subcontractor with Grant Award funds for any portion of the affected Relative's salary; or
 - (B) the Relative submits payment requests on behalf of the subcontractor to the Grant Recipient for payment with Grant Award funds.
 - (C) For exceptional circumstances, the Institute's Chief Executive Office may grant an exception to allow payment of Grant Award funds if the Grant Recipient notifies the Institute prior to finalizing the subcontract. The Chief Executive Officer must notify the Oversight Committee in writing of the decision to allow reimbursement for the otherwise unallowable expense.
 - (D) Nothing herein is intended to supersede a Grant Recipient's internal policies, to the extent that such policies are stricter.

(16) Fundraising.

(17) Tips or gratuities.

(f) Pursuant to Texas Health and Safety Code Section 102.203(b) the Institute may authorize reimbursement for one or more of the following expenses incurred by a cancer clinical trial participant that are associated with participating in a clinical trial and included in the Grant Recipient's Approved Budget:

(1) transportation, including car mileage, bus fare, taxi or ride hailing fare exclusive of tips, and commercial economy class airfare within the borders of the State of Texas;

(2) lodging, and

(3) any cost reimbursed under a cancer clinical trial participation program established pursuant to Texas Health and Safety Code Chapter 50 (relating to Cancer Clinical Trial Participation Program).

(g) [(f)] The Institute is responsible for making the final determination regarding whether an expense shall be considered an Allowable Cost.



CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

MEMORANDUM

TO: OVERSIGHT COMMITTEE MEMBERS
FROM: HEIDI MCCONNELL, CHIEF OPERATING OFFICER
SUBJECT: CHIEF OPERATING OFFICER REPORT
DATE: MAY 10, 2021

CPRIT Financial Overview for FY 2021 Quarter 2

FY 2021, Quarter 2 Operating Budget

CPRIT encumbered or expended 47% of the almost \$4.5 million budgeted in Indirect Administration and 86% of the approximately \$18 million budgeted in Grant Review and Award Operations. The Grant Review and Award Operations budget includes the majority of the agency's vendor contracts, including the \$9.9 million contract for grant management support services with GDIT.

CPRIT received \$122,845 in revenue sharing payments during the second quarter and another \$4,550 in April, the beginning of the third quarter. FY 2021 deposits total approximately \$172,000. Payments are deposited in the Cancer Prevention and Research Interest and Sinking Fund 5168. The cumulative total of payments received over the agency's lifetime exceeds \$4.8 million.

FY 2021, Quarter 2 Performance Measure Report

CPRIT reported on its two quarterly key performance measures to the Legislative Budget Board. CPRIT has not reported any company relocations to the state yet this year. For the number of people served through CPRIT's prevention and control grants, the measure's annual 500,000-person served target has almost been achieved in the first half of the year with 406,573 people served.

Debt Issuance History

In April 2021, TPFA issued \$68.9 million of general obligation commercial paper notes on CPRIT's behalf. This was the third tranche of commercial paper notes issued this fiscal year and supports grant award reimbursements. The remaining \$57.4 million of projected commercial paper notes needed for the year will be issued by June 2021.

FY 2022 Financial Audit Services Contract

CPRIT staff have concluded the evaluation of proposals received in response to the request for proposal to provide the agency with the annual audit of CPRIT financial statements and concluded that the contract should be awarded to McConnell & Jones LLP for an amount not to exceed \$38,500. McConnell & Jones is the incumbent vendor. CPRIT staff believes that the firm continues to offer the best value based on the agency's past experience with the firm completing

the audit in prior years as well as the firm's experience providing financial audit services to other state agencies and a state institution of higher education which underscores their knowledge and understanding of the state's general accounting processes and requirements.

Update on the State Auditor's Office (SAO) Audit of CPRIT's Grant Management Processes

The SAO audit team plans to wrap up the audit field work by early June. Once field work concludes, the audit team will present the results to the CPRIT staff including any possible findings. Once audit findings are finalized by the SAO and delivered to CPRIT, the agency will have an opportunity to provide management responses to address remediation of any identified audit findings. The SAO now anticipates releasing the audit report in August 2021.

Cancer Prevention and Research Institute of Texas
Quarterly Financial Report
As of February 28, 2021

Indirect Administration (B.1.1.)

	2021 Appropriated	2021 Budgeted	% of Total Budget	Actual Expenditures & Grant Encumbrances (FYTD)	Remaining Budget	Percent Expended	Estimated Expenditures (YTD)	Lapse/Overspent
1001 Salaries and Wages	\$ 1,787,425	\$ 1,787,425		\$ 692,800	1,094,625	39%	\$ 692,800	\$ 1,094,625
1002 Other Personnel Costs	38,785	38,785		9,043	29,742	23%	9,043	29,742
2001 Professional Fees and Services	1,808,662	1,900,943		1,028,333	872,610	54%	1,028,333	872,610
2003 Consumable Supplies	24,000	24,000		1,370	22,630	6%	1,370	22,630
2004 Utilities	58,600	58,600		33,085	25,515	56%	33,085	25,515
2005 Travel	45,000	45,000		-	45,000	0%	-	45,000
2006 Rent-Building	11,000	11,000		2,601	8,399	0%	2,601	8,399
2007 Rent-Machine and Other	32,172	32,172		26,000	6,172	81%	26,000	6,172
2009 Other Operating Expenses	554,409	574,409		303,366	271,043	53%	303,366	271,043
Subtotal - Indirect Administration (B.1.1.)	\$ 4,360,053	\$ 4,472,334	1.49%	\$ 2,096,596	\$ 2,375,738	47%	\$ 2,096,596	\$ 2,375,738

Grant Review and Award Operations (A.1.3.)

	2021 Appropriated	2021 Budgeted	% of Total Budget	Actual Expenditures & Grant Encumbrances (FYTD)	Remaining Budget	Percent Expended	Estimated Expenditures (YTD)	Lapse/Overspent
1001 Salaries and Wages	\$ 2,993,084	2,993,084		\$ 1,632,008	\$ 1,361,076	55%	\$ 1,632,008	\$ 1,361,076
1002 Other Personnel Costs	45,000	45,000		18,145	26,855	0%	18,145	26,855
2001 Professional Fees and Services	9,436,363	14,801,470		13,879,785	921,685	94%	13,879,785	921,685
2003 Consumable Supplies	-	-		-	-	0%	-	-
2004 Utilities	12,000	12,000		6,228	5,772	52%	6,228	5,772
2005 Travel	65,000	45,000		-	45,000	0%	-	45,000
2009 Other Operating Expenses	355,283	131,567		7,993	123,574	6%	7,993	123,574
Subtotal - Grant Operations (A.1.3.)	\$ 12,906,730	\$ 18,028,121	6.02%	\$ 15,544,160	\$ 2,483,961	86%	\$ 15,544,160	\$ 2,483,961

Grants

	2021 Appropriated	2021 Budgeted	% of Total Budget	Actual Expenditures & Grant Encumbrances (FYTD)	Remaining Budget	Percent Expended	Estimated Expenditures (YTD)	Lapse/Overspent
4000 Grants - Prevention (A.1.2)	\$ 28,050,081	\$ 28,080,479		\$ -	\$ 28,080,479	0%	\$ -	\$ 28,080,479
4000 Grants - Research (A.1.1.)	251,620,104	\$ 249,135,528		-	\$ 249,135,528	0%	-	249,135,528
Subtotal - Grants	\$ 279,670,185	\$ 277,216,007	92.49%	\$ -	\$ 277,216,007	0%	\$ -	\$ 277,216,007
Grand Totals	\$ 296,936,968	\$ 299,716,462	100.00%	\$ 17,640,756	\$ 282,075,706	6%	\$ 17,640,756	\$ 282,075,706

102306

Cancer Prevention and Research Institute of Texas
Cancer Prevention and Research Institute Fund Account - 5136
As of February 28, 2021

	<u>2/01/2021- 2/28/2021</u>	<u>AY 21 Year to Date as of 2/28/2021</u>
<u>Beginning Balance : 9/01/2020</u>		\$ 600,506
Increases:		
(1)	\$ -	\$ -
(2)	-	
Total Increases	<u>\$ -</u>	<u>\$ 600,506.00</u>
Reductions:		
Expenditures - Appropriated	\$ -	\$ -
	\$ -	\$ -
	\$ -	\$ -
Total Reductions	<u>\$ -</u>	<u>\$ -</u>
<u>Ending Balance, 2/28/2021</u>		<u><u>\$ 600,506.00</u></u>

Note: (1) The Institute received a settlement from the Texas Cancer Coalition (TCC). This amount represents the final distribution and transfer of all funds (\$303,877) from the TCC which ceased operations in May 2013. These funds are in the State Treasury but are not appropriated to CPRIT. The beginning balance reflects the transfer of all TCC funds.

Cancer Prevention and Research Institute of Texas
License Plate Trust Fund Account - 0802
As of February 28, 2021

	<u>2/01/2021- 2/28/2021</u>	<u>AY 21 Year to Date as of 2/28/2021</u>
<u>Beginning Balance : 9/01/2020</u>		\$ 30,397.95
Increases:		
(1) License Plate Revenue Received	\$ 942.32	\$ 4,146.88
 Total Increases	 <u>\$ 942.32</u>	 <u>\$ 34,544.83</u>
Reductions:		
Expenditures - Appropriated	\$ -	\$ -
	-	-
 Total Reductions	 <u>\$ -</u>	 <u>\$ -</u>
 <u>Ending Balance, 2/28/2021</u>		 <u><u>\$ 34,544.83</u></u>

Note:

Balance forward from 2020 License Plate \$30,397.95

12-5

Cancer Prevention and Research Institute of Texas

Appropriated Receipts - 666

As of February 28, 2021

	<u>2/01/2021- 2/28/2021</u>	<u>AY 21 Year to Date as of 2/28/2021</u>
<u>Beginning Balance : 9/01/2020</u>		\$ 83,996.90
Increases:		
(1) Product Development Application Fees Received	\$ 21,500.00	\$ 21,500.00
(2) Appropriated Receipts applied to payments	\$ -	\$ -
(3) Conference Registration Fees	\$ -	\$ -
(4) Conference Registration Fees-Credit Card	\$ -	\$ -
Total Increases	<u>\$ 21,500.00</u>	<u>\$ 21,500.00</u>
Reductions:		
Conference Expenditures - Appropriated	\$ -	\$ -
Credit Card Fees Expended	\$ -	\$ -
Refund-Application Fees	\$ -	\$ -
Legal Services Expenses (Application Fees)	\$ -	\$ -
Total Reductions	<u>\$ -</u>	<u>\$ -</u>
<u>Ending Balance, 2/28/2021</u>		<u><u>\$ 105,496.90</u></u>

Forward balance for FY 2020 is \$83,896.90
Application Fees + \$100 Donation

Cancer Prevention and Research Institute of Texas
Interest & Sinking Fund Account - 5168
As of February 28, 2021

	<u>2/01/2021- 2/28/2021</u>	<u>AY 21 Year to Date as of 2/28/2021</u>
<u>Beginning Balance : 9/01/2020</u>		\$ 2,237,500.68
Increases:		
(1) Revenue Sharing / Royalties	\$ 22,845.32	\$ 67,654.71
Total Increases	<u>\$ 22,845.32</u>	<u>\$ 2,305,155.39</u>
Reductions:		
Expenditures - Appropriated	\$ -	\$ -
	\$ -	
	\$ -	\$ -
Total Reductions	<u>\$ -</u>	<u>\$ -</u>
<u>Ending Balance, 2/28/2021</u>		<u><u>\$ 2,305,155.39</u></u>

Balance forward from FY 2019 is \$2,237,500.68

**Cancer Prevention and Research Institute of Texas
FY 2021, Quarter 2 Performance Measure Report**

Measure	Targeted Performance	QTR 1	QTR 2	QTR 3	QTR 4	Sum of QTRs	% of Mandate Attained
Number of People Served by Institute Funded Prevention and Control Activities	500,000	234,404	172,169	-	-	406,573	81.31%
Number of Entities Relocating to TX for Cancer Research Related Projects	1	0	0	-	-	0	0.00%
Annual Age-adjusted Cancer Mortality Rate	145.2	N/A	N/A	N/A	N/A	0	0.00%
Number of Published Articles on CPRIT-Funded Research Projects	1,000	N/A	N/A	N/A	N/A	0	0.00%
Number of New Jobs Created and Maintained	1,500	N/A	N/A	N/A	N/A	0	0.00%

Variance Explanations

Number of People Served by Institute Funded Prevention and Control Activities

CPRIT prevention grantees have continued to be successful at delivering cancer prevention education and clinical services to more people than they anticipated, stretching their CPRIT-grant funds further to serve Texans. During the COVID-19 pandemic, they found alternative means through the use of remote technologies such as the telephone, electronic messages, and videoconferencing, to continue delivering cancer prevention education to Texans. They have also resumed providing cancer prevention clinical services, such as mammograms and colonoscopies, following COVID-19 precautions which include the use of COVID-19 tests and a greater amount of PPE.

Number of Entities Relocating to TX for Cancer Research Related Projects

This output is dependent on the number of companies applying for CPRIT Company Awards that can successfully advance through CPRIT's rigorous review and evaluation process, receive an award and actually relocate operations to Texas. Therefore, the results vary. A company must meet 4 of CPRIT's 7 criteria for a relocation to be considered complete.

CPRIT Commercial Paper and G.O. Bond Issuance

Fiscal Year	Amount Appropriated	Dated Issued	Amount Issued	Amount Issued for Fiscal Year	Commercial Paper or GO Bond Issuance	Series	Comments	Interest Rate
2010	\$ 225,000,000	September 9, 2009	\$ 9,100,000		Commercial Paper Notes	Series A, Taxable	Refunded as G.O. Bonds	
2010		September 9, 2009	\$ 3,600,000		Commercial Paper Notes	Series B, Tax-Exempt	Defeased with cash July 2011	
2010		March 12, 2010	\$ 63,800,000		Commercial Paper Notes	Series A, Taxable	Refunded as G.O. Bonds	
2010		August 26, 2010	\$ 148,500,000		Commercial Paper Notes	Series A, Taxable	Refunded as G.O. Bonds	
				\$ 225,000,000				
2011	\$ 225,000,000	September 7, 2010	\$ 11,800,000		Commercial Paper Notes	Series A, Taxable		
2011		August 10, 2011	\$ 51,000,000		G.O. Bonds	Taxable Series 2011	Par amount of new money	Fixed Rate Bonds All-In-True Interest Cost 4.0144%
2011		August 10, 2011	\$ 232,045,000		G.O. Bonds (Refunding Bonds)	Taxable Series 2011	Par amount of refunding; Refunded \$233.2M of GOCP CPRIT Series A (9/9/09, 3/12/09, 8/26/09, 9/7/10)	Fixed Rate Bonds All-In-True Interest Cost 4.0144%
				\$ 62,800,000				
2012	\$ 300,000,000	September 7, 2011	\$ 3,200,000		Commercial Paper Notes	Series A, Taxable	Refunded as G.O. Bonds	
2012		December 8, 2011	\$ 3,200,000		Commercial Paper Notes	Series A, Taxable	Refunded as G.O. Bonds	
2012		March 2, 2012	\$ 12,300,000		Commercial Paper Notes	Series A, Taxable	Refunded as G.O. Bonds	
2012		June 21, 2012	\$ 15,000,000		Commercial Paper Notes	Series A, Taxable	Refunded as G.O. Bonds	
2012		August 16, 2012	\$ 42,000,000		Commercial Paper Notes	Series A, Taxable	Refunded as G.O. Bonds	
				\$ 75,700,000				
2013	\$ 300,000,000	September 6, 2012	\$ 9,600,000		Commercial Paper Notes	Series A, Taxable	Refunded as G.O. Bonds	
2013		May 16, 2013	\$ 13,400,000		Commercial Paper Notes	Series A, Taxable	Refunded as G.O. Bonds	
				\$ 23,000,000				
2014	\$ 300,000,000	November 25, 2013	\$ 55,200,000		Commercial Paper Notes	Series A, Taxable	Refunded as G.O. Bonds	
2014		March 13, 2014	\$ 47,000,000		Commercial Paper Notes	Series A, Taxable	Refunded as G.O. Bonds	
2014		June 17, 2014	\$ 60,300,000		Commercial Paper Notes	Series A, Taxable	Refunded as G.O. Bonds	
2014		July 8, 2014	\$ 233,280,000		G.O. Bonds (Refunding Bonds)	Taxable Series 2014	Par amount of refunding; Refunded \$237.88M of GOCP CPRIT Series A	Fixed Rate Bonds All-In-True Interest Cost 3.327184%
				\$ 162,500,000				
2015	\$ 300,000,000	November 5, 2014	\$ 57,600,000		Commercial Paper Notes	Series A, Taxable	Refunded as G.O. Bonds	
2015		April 29, 2014	\$ 112,000,000		Commercial Paper Notes	Series A, Taxable	Refunded as G.O. Bonds	
2015		June 26, 2015	\$ 75,000,000		Commercial Paper Notes	Series A, Taxable	Refunded as G.O. Bonds	
				\$ 244,600,000				
2016	\$ 300,000,000	September 22, 2015	\$ 55,400,000		Commercial Paper Notes	Series A, Taxable		
2016		October 29, 2015	\$ 300,000,000		G.O. Bonds (Refunding Bonds)	Taxable Series 2015C	Par amount of refunding; Refunded \$300M of GOCP CPRIT Series A	Fixed Rate Bonds All-In-True Interest Cost 3.299867%
2016		October 29, 2015	\$ 69,800,000		G.O. Bonds	Taxable Series 2015C	Par amount of new money: Disbursed to CPRIT January 2016	Fixed Rate Bonds All-In-True Interest Cost 3.299867%
2016		May 16, 2016	\$ 92,100,000		Commercial Paper Notes	Series A, Taxable	Refunded as G.O. Bonds	
2016		August 29, 2016	\$ 60,000,000		Commercial Paper Notes	Series A, Taxable	Refunded as G.O. Bonds	

CPRIT Commercial Paper and G.O. Bond Issuance

Fiscal Year	Amount Appropriated	Dated Issued	Amount Issued	Amount Issued for Fiscal Year	Commercial Paper or GO Bond Issuance	Series	Comments	Interest Rate
				\$ 277,300,000				
2017	\$300,000,000	October 19, 2016	\$ 58,000,000		Commercial Paper Notes	Series A, Taxable	Refunded as G.O. Bonds	
2017		January 5, 2017	\$ 58,900,000		Commercial Paper Notes	Series A, Taxable	Refunded as G.O. Bonds	
2017		February 8, 2017	\$ 269,000,000		G.O. Bonds (Refunding Bonds)	Taxable Series 2017	Par amount of refunding: Refunded \$269M of GOCP CPRIT Series A	Fixed Rate Bonds All-In-True Interest Cost 3.4622%
2017		February 8, 2017	\$ 106,000,000		G.O. Bonds	Taxable Series 2017	Par amount of new money	Fixed Rate Bonds All-In-True Interest Cost 3.4622 %
				\$ 222,900,000				
2018	\$300,000,000	September 29, 2017	\$ 68,200,000		Commercial Paper Notes	Series A, Taxable	Refunded as G.O. Bonds	
2018		March 8, 2018	\$ 99,000,000		Commercial Paper Notes	Series A, Taxable	Refunded as G.O. Bonds	
2018		July 11, 2018	\$ 55,000,000		Commercial Paper Notes	Series A, Taxable	Refunded as G.O. Bonds	
				\$ 222,200,000				
2019		September 21, 2018	\$ 222,200,000		G.O. Bond (Refunding Bonds)	Taxable Series 2018	Par amount of refunding: Refunded \$222.2M of GOCP CPRIT Series A	Fixed Rate Bonds All-In-True Interest Cost 3.720632%
2019	\$300,000,000	September 21, 2018	\$ 75,975,000		G.O. Bonds	Taxable Series 2018	Par amount of new money	Fixed Rate Bonds All-In-True Interest Cost 3.720544%
2019		March 28, 2019	\$ 77,725,000		Commercial Paper Notes	Series A, Taxable		Interest rates between 1.90% - 2.55%
2019		July 12, 2019	\$ 54,000,000		Commercial Paper Notes	Series A, Taxable		Interest rates between 1.95% - 2.35%
				\$ 207,700,000				
2020		September 16, 2019	\$ 64,300,000		Commercial Paper Notes	Series A, Taxable		Interest rate of 2.10%
2020		January 9, 2020	\$ 52,000,000		Commercial Paper Notes	Series A, Taxable		
2020		April 23, 2020	\$ 248,025,000		G.O. Bond (Refunding Bonds)	Taxable Series 2018	Par amount of refunding: Refunded \$243.025M of GOCP CPRIT Series A	Fixed Rate Bonds All-In-True Interest Cost 2.644360%
2020		April 23, 2020	\$ 115,000,000		G.O. Bonds	Taxable Series 2018	Par amount of new money	Fixed Rate Bonds All-In-True Interest Cost 2.644360%
				\$ 231,300,000				
2021	\$300,000,000	September 11, 2020	\$ 75,000,000		Commercial Paper Notes	Series A, Taxable		Interest rate of 0.23% for 90 days
		January 14, 2021	\$ 59,000,000		Commercial Paper Notes	Series A, Taxable		Interest rate of 0.23% for 118 days
		April 29, 2021	\$ 68,900,000		Commercial Paper Notes	Series A, Taxable		Interest rate of 0.18% for 90 days
				\$ 202,900,000				
TOTAL ISSUED TO DATE				\$ 2,157,900,000				



CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

MEMORANDUM

TO: OVERSIGHT COMMITTEE MEMBERS
FROM: HEIDI MCCONNELL, CHIEF OPERATING OFFICER
SUBJECT: GRANT MANAGEMENT SUPPORT SERVICES CONTRACT AWARD
DATE: MAY 10, 2021

Recommendation

CPRIT staff recommends that the agency award a contract to General Dynamics Information Technology, Inc. (GDIT) for a FY 2022 amount not to exceed \$9,574,549. This amount includes an annual payment of \$1.1 million as a subscription to the grant management platform (GMP) with access to the application receipt, peer review evaluation, and post-award grant contract and report management modules in the platform. The remaining \$8,474,549 is an estimate of the time and materials that will be expended by GDIT on labor and direct costs for peer review meetings. Except for the GMP subscription, CPRIT pays only for actual services received and direct costs incurred by GDIT up to the contracted price.

Of note, there are no in-person peer review meetings planned for either major grant award cycle during FY 2022. All peer review meetings will again be held using remote video technology, so contract pricing includes only the use of the remote video technology and honoraria payments to peer review panel members for these meetings.

Because this contract exceeds \$1 million, the Legislative Budget Board (LBB) must also approve the contract before CPRIT will be able to execute it.

Background

GDIT submitted a thorough proposal in response to the requirements for end-to-end grant management support services in CPRIT's request for proposal published February 25, 2021. The company possesses the necessary experience in comprehensive grant management and peer review solutions based on the experience of their scientific staff, their existing grant administration processes and know-how, and information technology infrastructure and technical support.

GDIT has a complete suite of software applications to support the pre-award grant processes including application receipt and comprehensive peer review management as well as the post-award management of grant contracts and reporting requirements. It has significant experience providing similar grant management services to the U.S. Army Medical Research and Development Command Congressionally Directed Medical Research Programs. GDIT also provides different components of grant management or related information technology support to

two other federal agencies, the Department of Education Institute of Education Sciences and the Department of Justice Office of Justice Programs.

Therefore, CPRIT believes the recommended contract represents the best value to the agency based on the vendor's depth and breadth of experience and capabilities.

GDIT is the incumbent vendor for grant management support services. Prior to GDIT's acquisition of both SRA International, Inc. and CSRA LLC in April 2018, CPRIT has contracted with one of those companies to provide the agency with grant management support services since the initial contract awarded to SRA International, Inc. in June 2009.

GDIT services include:

- Logistical support for peer review meeting arrangements whether conducted in-person, by teleconference, or by using remote video technology;
- Administrative support for peer review panel honoraria payments, travel arrangements to in-person meetings, and travel expense reimbursements (when applicable);
- Summarized evaluation reports for each grant application including peer review chair consensus statements, budget recommendations, and noted issues in clinical trials with human subjects or animal research;
- A Software as a Service (SaaS) subscription to the Grants Management Platform (GMP) software including the application receipt module, program and peer review module, and grant management module;
- Incorporation of grant request for application requirements in the GMP application receipt module for electronic application submission;
- Enhancements to the GMP grant management module for improved data collection, reporting, and security;
- Enhancements to the GMP program and peer review module for improved data security;
- Administration of electronic grant application pedigrees; and
- Scientific expertise for the evaluation of the annual and final progress reports for academic research grants.



CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

MEMORANDUM

TO: OVERSIGHT COMMITTEE MEMBERS
FROM: HEIDI MCCONNELL, CHIEF OPERATING OFFICER
SUBJECT: FY 2022 REQUEST FOR FINANCING OF CPRIT BONDS
DATE: MAY 10, 2021

Recommendation

CPRIT staff recommends that the Oversight Committee approve the attached resolution for a request for financing to the Texas Public Finance Authority (TPFA) to issue debt on behalf of CPRIT in fiscal year 2022. The amount to be financed will not exceed \$300 million in bond proceeds appropriated to CPRIT for its operations and prevention and research grant awards. I estimate that CPRIT will request TPFA issue \$298.1 million in commercial paper notes during fiscal year 2022 to pay for agency operating expenses, the transfer to the Department of State Health Services for the Texas Cancer Registry, and grant reimbursements or authorized advances related to awards made in fiscal years 2015-2022.

Background

TPFA has issued approximately \$2.2 billion in general obligation debt, both long-term general obligation bonds and short-term commercial paper notes, on behalf of CPRIT through April 2021 since the agency's inception.



CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

A RESOLUTION AUTHORIZING A REQUEST FOR FINANCING AND THE EXECUTION AND DELIVERY OF DOCUMENTS REQUIRED TO EFFECT SUCH FINANCING

Whereas, the Texas Public Finance Authority (the "Authority") is authorized to issue general obligation bonds to finance the grant program for cancer research and prevention and control for the use and benefit of the Cancer Prevention & Research Institute of Texas (the "Agency") pursuant to Article III, Section 67, Texas Constitution; Texas Health & Safety Code, Chapter 102, as amended; and Texas Government Code, Chapter 1232, as amended, (collectively, the "Authorizing Law");

Whereas, the Agency desires and intends to request the Authority to finance the costs of the program as permitted by the Authorizing Law; and

Whereas, the Agency recognizes that in order to finance the cost of the program, the Authority may issue short term obligations, general obligation bonds, either or both ("Obligations") in an aggregate principal amount sufficient to finance program costs in the estimated amount of \$300,000,000, plus the costs of issuance and related administrative costs, if any, which will be determined at the time of issuance; and

Whereas, the form of a Request for Financing, dated as of May 19, 2021, (the "Request for Financing") from the Agency to the Authority, which includes a detailed description of the program to be financed for the Agency ("program" herein) and a proposed expenditure schedule is presently before the CPRIT Oversight Committee.

NOW THEREFORE BE IT RESOLVED by the CPRIT Oversight Committee that:

Section 1. The purpose of the financing is to provide funds sufficient to make grant awards for cancer research and prevention and control and for the operations of the Agency, and the financing thereof is appropriate at this time. Accordingly, the execution and delivery of the Request for Financing to the Authority pursuant to the Authorizing Law is hereby ratified, approved and confirmed.

Section 2. The Chief Executive Officer of the Agency is hereby empowered, authorized and directed to:

- a. sign and deliver any and all documents necessary or desirable to effect the financing and provide the projects, which may include but not be limited to a Memorandum of Understanding and a Financing Agreement between the Agency and the Authority;

- b. cooperate with the Authority and its consultants to prepare an Official Statement in connection with the sale of the Obligations;
- c. and to take any other action necessary to assist in such sale.

Section 3. All actions not inconsistent with provisions of this Resolution heretofore taken by the Institute and the Chief Executive Officer or designee thereof and the other officers of, or consultants to the Institute, directed toward the financing of the Program, and the issuance of the Obligations are hereby ratified, approved and confirmed.

Section 4. The officers and employees of the Agency shall take all action in conformity with the Authorizing Law and the provisions of the General Appropriations Act, 87th Legislature, R.S. (2021) to effect the issuance of the Obligations and complete the Program as provided in the Agreement and take all action necessary or desirable or in conformity with the Authorizing Law for carrying out, giving effect to, and consummating the transactions contemplated by the Memorandum of Understanding, the Agreement, the Obligations, and this Request for Financing, including without limitation, the execution and delivery of any closing documents in connection with the closing of the Obligations.

Section 5. This Resolution was adopted at a meeting open to the public, and public notice of the time, place and purpose of said meeting was given, all as required by Ch. 551, Texas Government Code.

Adopted by the affirmative vote of a majority of the Cancer Prevention and Research Institute of Texas Oversight Committee present and voting on this 19th day of May, 2021.

Cancer Prevention and Research Institute
of Texas Oversight Committee

Attested:

Donald “Dee” Margo
Presiding Officer

David A. Cummings, M.D.
Secretary



CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

Fiscal Year 2022 Request for Financing Program Description

Purpose

The Cancer Prevention and Research Institute of Texas (CPRIT) is the state agency mandated to:

- 1) create and expedite innovation in the area of cancer research and in enhancing the potential for a medical or scientific breakthrough in the prevention of cancer and cures for cancer;
- 2) attract, create, or expand research capabilities of public or private institutions of higher education and other public or private entities that will promote a substantial increase in cancer research and in the creation of high-quality new jobs in this state; and
- 3) develop and implement the Texas Cancer Plan.

Powers and Duties

CPRIT will make grants to provide funds to public or private persons to implement the Texas Cancer Plan, and make grants to institutions of learning and to advanced medical research facilities and collaborations in this state for:

- 1) research into the causes of and cures for all types of cancer in humans;
- 2) facilities for use in research into the causes of and cures for cancer;
- 3) research, including translational research, to develop therapies, protocols, medical pharmaceuticals, or procedures for the cure or substantial mitigation of all types of cancer in humans; and
- 4) cancer prevention and control programs in this state to mitigate the incidence of all types of cancer in humans.

Implementation Plan

CPRIT estimates that \$298.1 million in bonds proceeds must be issued on an as-needed basis consistent with Texas Government Code, Chapter 1232 to cover grant award obligations from fiscal years 2015, 2016, 2017, 2018, 2019, 2020, 2021, and 2022 and operating costs for general agency administration and pre- and post-award grants management processes.

During fiscal year 2022, CPRIT will use the bond proceeds to disburse grant funds for grants awarded by CPRIT during fiscal years 2015, 2016, 2017, 2018, 2019, 2020, 2021, and 2022. CPRIT is authorized to obligate approximately \$275.9 million for cancer prevention and research grant awards in fiscal year 2022.

CPRIT announces grant awards for cancer prevention education and service programs and academic and product development cancer research programs four times per year. CPRIT

anticipates that it will obligate the available \$275.9 million for cancer prevention, product development research, and academic research grants.

Grant funds are generally disbursed quarterly on a reimbursement basis to grant recipients. For product development research grant awards, CPRIT may advance funds to provide recipients of those types of awards with working capital to meet their research milestones or objectives.

CPRIT is authorized to use bond proceeds to fund its grant review and award operations and indirect administration costs. At this time, the approximate budgeted amount of these two categories is \$21 million in bond proceeds for fiscal year 2022 based on the appropriations provided in the General Appropriations Act (Senate Bill 1), 87th Legislature. CPRIT must transfer \$3.1 million in bond proceeds to the Texas Department of State Health Services (DSHS) for the operating costs associated with the Texas Cancer Registry. From the total of all the agency's operating costs, CPRIT requires half of the proceeds to be available at the beginning of the state fiscal year to be able to cover the operating expenses for six months. CPRIT also requires proceeds at the beginning of each state fiscal quarter to pay for award costs reimbursed to grant recipients for the previous state fiscal quarter.

The academic research program provides awards in the following areas: cancer biology, cancer genetics, immunology, imaging, therapeutics, prevention/epidemiology, and informatics/computation. The product development research program focuses awards on the development of cancer drugs, diagnostics, and devices based on discoveries made in one of the seven areas described above. Prevention program grants are awarded for cancer prevention information and services, early detection and treatment, professional education and practice, cancer data acquisition and utilization, or survivorship (the areas of the Texas Cancer Plan). Awards for all programs are issued for multiple years, ranging from two to five years.

CPRIT has established a grant process that allows grant proposals for cancer prevention, academic research, and product development research to be submitted through requests for applications (RFA) issued throughout each fiscal year. All proposals are reviewed by multiple experts in the appropriate area. CPRIT has approximately 200 national experts in cancer prevention, academic research, and product development research to review proposals and provide funding recommendations to CPRIT.

The award recommendations developed by the peer review committees are forwarded to the Program Integration Committee (PIC) for consideration. The five members of the PIC are statutorily defined as the Chief Executive Officer (CEO), Chief Scientific Officer, Chief Prevention Officer, Chief Product Development Officer, and DSHS Commissioner. The PIC finalizes award recommendations across all programs prior to every Oversight Committee meeting. When those proposed awards are forwarded to the Oversight Committee, each recommended award is accompanied by an affidavit signed by the CEO to affirm that the award followed all required pre-award grant procedures. The Oversight Committee considers these recommendations and votes to approve the awards.

CPRIT Program Description Appendix: Appropriation and Debt History

Fiscal Year	2010	2011	2012	2013^	2014	2015	2016	2017	2018	2019	2020	2021*	2022**	TOTAL
GAA Appropriations	\$ 225,000,000	\$ 225,000,000	\$ 300,000,000	\$ 300,000,000	\$ 300,000,000	\$ 300,000,000	\$ 300,000,000	\$ 300,000,000	\$ 300,000,000	\$ 300,000,000	\$ 300,000,000	\$ 300,000,000	\$ 300,000,000	\$ 3,450,000,000
BRB-Approved Debt	\$ 225,000,000	\$ 225,000,000	\$ 300,000,000	\$ 300,000,000	\$ 300,000,000	\$ 300,000,000	\$ 300,000,000	\$ 300,000,000	\$ 300,000,000	\$ 300,000,000	\$ 300,000,000	\$ 300,000,000	\$ -	\$ 3,450,000,000
Total Value of Grant Awards Contracted	\$ 216,122,105	\$ 210,651,285	\$ 269,354,368	\$ 105,493,808	\$ 255,834,556	\$ 269,707,850	\$ 278,191,276	\$ 272,030,746	\$ 256,281,743	\$ 236,076,753	\$ 254,604,570	\$ -	\$ -	\$ 2,624,349,060
Agency Operations and Transfer to DSHS (Cancer Registry)	\$ 8,866,523	\$ 11,773,670	\$ 18,591,666	\$ 16,750,815	\$ 20,492,668	\$ 22,525,206	\$ 20,341,154	\$ 19,770,432	\$ 19,707,288	\$ 20,196,337	\$ 22,766,115	\$ 23,277,916	\$ 24,145,308	\$ 262,205,098
Total Agency Expenses Obligated	\$ 224,988,628	\$ 222,424,955	\$ 287,946,034	\$ 122,244,623	\$ 276,327,224	\$ 292,233,056	\$ 298,532,430	\$ 291,801,178	\$ 275,989,031	\$ 256,273,090	\$ 277,370,685	\$ 23,277,916	\$ 24,145,308	\$ 2,886,554,158
Issued Debt to Date	\$ 225,000,000	\$ 222,451,288	\$ 287,981,794	\$ 122,244,623	\$ 273,556,273	\$ 272,815,409	\$ 240,850,525	\$ 183,257,813	\$ 131,612,339	\$ 75,385,121	\$ 41,592,031	\$ 22,425,191	\$ -	\$ 2,099,172,407
Unobligated Bond Authority Appropriations	\$ -	\$ 2,575,045	\$ 12,053,966	\$ 177,755,377	\$ 23,672,776	\$ 7,766,944	\$ 1,467,570	\$ 8,198,822	\$ 24,010,969	\$ 43,726,910	\$ 19,856,976	\$ -	\$ -	\$ 321,085,355
Remaining Balances in Closed Grant Contract (Available for Deobligation)	\$ 38,525,292	\$ 9,032,975	\$ 13,321,630	\$ 3,397,268	\$ 7,621,741	\$ 4,846,577	\$ 14,251	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ 76,759,734
Unbudgeted ERS Cash Transfer for DSHS Retired Employee Insurance Payments	\$ (10,779)	\$ (11,953)	\$ (103,591)	\$ (91,534)	\$ (134,151)	\$ (129,694)	\$ (139,609)	\$ (156,337)	\$ (166,003)	\$ (389,362)	\$ (116,920)	\$ -	\$ -	\$ (1,449,933)

*Current state fiscal year
 **Upcoming state fiscal year under consideration by the 87th Texas Legislature.
 *State leadership moratorium on CPRIT grant awards.



CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

TO: OVERSIGHT COMMITTEE MEMBERS
FROM: CHRIS CUTRONE, SENIOR COMMUNICATIONS SPECIALIST
SUBJECT: COMMUNICATIONS UPDATE
DATE: MAY 10, 2021

The following is an overview of the agency's communication activities from February 2021 to May 2021.

Media Summary

A press release announcing the hire of Tracey Davies as CPRIT's new Chief Strategic Initiatives and Intellectual Property Officer was sent out on Monday March 1. Quorum Report's People on the Move and Texas Government Insider both carried excerpts.

On March 23, a press release was sent out discussing how the organizations that provide cancer screenings funded by CPRIT report encouraging signs of recovery after experiencing a precipitous decline in the number of Texans receiving routine cancer screenings due to the COVID-19 pandemic.

Houston Chronicle health care reporter Todd Ackerman has retired and is now a writer at Houston Methodist.

Coverage:

- 3 articles featured CPRIT
- 20 additional articles mentioned CPRIT (stories primarily focused on work of grantees)

Coverage Highlights (see clipped articles following report):

- February 12, 2021: "*Bristol Myers Squibb pens \$1.3B biobucks pact with Molecular Templates, axes Celgene CAR-T asset*"- BioSpace
- February 22, 2021: "*Houston oncology co. Iterion Therapeutics raises \$17M for clinical trials*" – Houston Business Journal
- February 26, 2021: "*UT Health San Antonio gets \$6 million grant for DNA cancer research from state agency*" – San Antonio Express-News
- March 2, 2021: "*Impact of Running Reaches Marrow to Spark Bone Growth in Mice*" – The Scientist

- March 12, 2021: *“Breakthrough research at UT Austin is protecting the world against COVID-19” – Dallas Morning News*
- May 5, 2021: *“AI, digital health feature in latest batch of FDA breakthrough device designations” – MedTech Dive*

Social Media

We promoted on social media the March 9th panel "Science Sparks: Big Strides in Fighting Cancer" with Nobel Laureate Dr. James Allison and Dr. Livia Eberlin hosted by the Texas Science Fest at the College of Natural Sciences at UT Austin. Dr. Willson moderated the panel.

With March being Colorectal Cancer Awareness Month, social media activities revolved around promoting our grantees' work in this area. We also did social media for International HPV Awareness Day (March 4) and World Kidney Day (March 11).

April was National Minority Cancer Awareness Month, and a number of our grantees and projects were the focus of our social media posts, such as the work of Christopher Flowers of MD Anderson, the Liver Cancer CAP, and a Baylor College of Medicine screening program for underserved communities.

We also produced a video featuring cancer survivor Janice Robbins from the Moncrief Cancer Institute. She spoke about how their CPRIT-funded programs saved her life. The video was posted on our social media channels, and can be viewed here:
https://www.youtube.com/watch?v=b98fe0_4xnQ

National Oral, Head, and Neck Cancer Awareness Week was April 12-16, and it was one of our more successful social weeks, especially on Twitter. We had numerous retweets and likes, driven by stakeholders and advocates. Posts were on OncoNano, Jane Montealegre of BCM and Perimeter's FDA device approval. Testicular Cancer Awareness Month was also the subject of a post on the work of Aditya Bagrodia of UT Southwestern.

May is also a busy month for cancer awareness, and we have already observed Melanoma Monday (May 3) and National Ovarian Cancer Awareness Day (May 8). We plan to run posts for National Cancer Research Month, Women's Health Week, Brain Cancer Awareness Month and Clinical Trials Awareness Day.

Social media statistics for the past month are below.

Twitter (April 13, 2021- May 10, 2021):

- Total Tweets: 13
- Tweet Impressions: 23.4K
- Profile Visits: 1,319
- Mentions: 15
- New Followers: 25 (2,842 total)
- Top tweet: Tobacco & HPV are known causes of oral, head & neck cancers. Dr. Jane

Montealegre of [@bcmhouston](#) leads efforts against both in [@harrishealth](#) clinics by improving HPV vaccine completion rates in underserved youth and screening them for tobacco use: [#OHANCAW](https://cprit.us/3df9jJt)

- Impressions: 5,685 people
Engagements: 106

LinkedIn (April 11, 2021-May 10, 2021):

- Total Updates: 12
- Reactions: 43
- Page views: 117
- Unique Visitors: 62
- New followers: 17 (1,185 total)
- Top Update: Our congratulations go to Dr. Jonathan Sessler of the [College of Natural Sciences, UT Austin](#) on his election to the [National Academy of Sciences](#). CPRIT has awarded him \$6.9 million in grants to research the resistance to platinum chemotherapy by multiple cancer sites, such as ovarian & non-small cell lung cancers. <https://cprit.us/2QyVpcE>
Impressions: 212 people

Facebook (April 12, 2021-May 9, 2021):

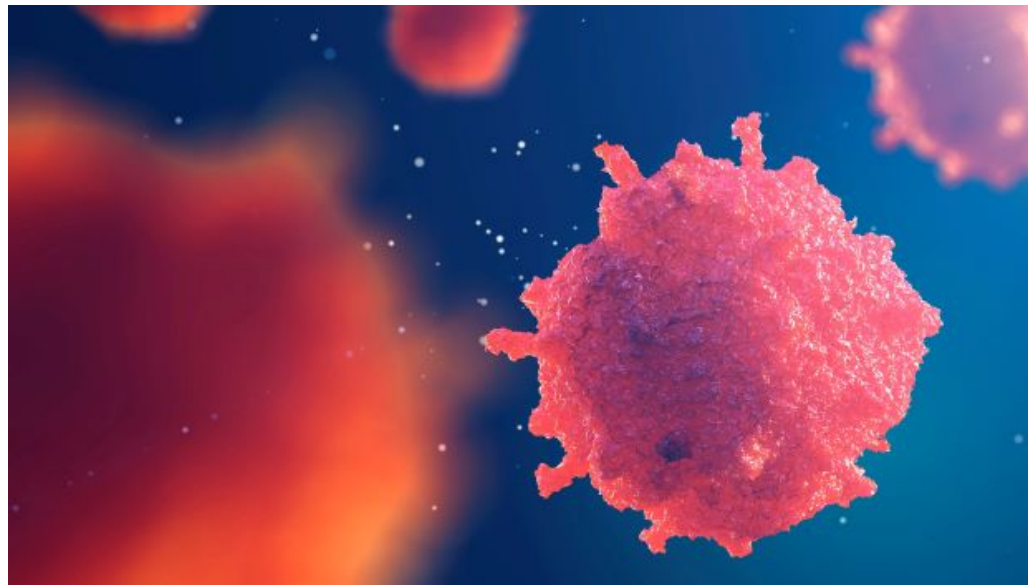
- Total posts: 15
- Reach: 1.6K users
- Engagement: 633 reactions/clicks
- Page Views: 127
- Top Post: Tobacco and HPV are known causes of oral, head and neck cancers. Dr. Jane Montealegre of [Baylor College of Medicine](#) is leading efforts against both. In eight [Harris Health System](#), her efforts have led to an 80% HPV vaccine series completion rate among underserved youth - up from 46%. At the clinics, patients are screened for e-cigarette use and tobacco prevention materials are distributed as they wait following vaccinations. Read more about her program: [#OHANCAW](https://cprit.us/3df9jJt)
Post Reach: 751 users
Engagement: 179 clicks, 265 reactions

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Molecular Templates Forges Cancer Deal with BMS Worth up to \$1.3 Billion

Published: Feb 12, 2021 | By Alex Keown



Texas-based **Molecular Templates** (MTEM) and **Bristol Myers Squibb** forged a strategic research collaboration worth a potential \$1.3 billion to discover and develop multiple oncology therapies using a next-generation engineered toxin body (ETB) platform.

The ETB technology platform was developed by Molecular Templates. ETBs represent a new class of targeted therapeutics that act through differentiated mechanisms of actions including the ability to force receptor internalization, deliver therapeutic payloads, and directly kill targeted cells through the enzymatic inactivation of ribosomes, the company said.

Both BMS and Molecular Templates hope they will be able to discover new molecules with the ETB platform. According to MTEM, ETBs use a genetically engineered form of Shiga-like Toxin A subunit, or SLTA, a ribosome inactivating bacterial protein, that can be targeted to specifically destroy cancer cells.

Eric Poma, chief executive and scientific officer for Molecular Templates, touted the partnership with BMS and its strong oncology franchise.

“MTEM is excited to be working with Bristol Myers Squibb to focus on discovering and developing new ETBs against promising oncology targets. This collaboration provides further validation of our ETB platform while we continue to advance our wholly-owned product pipeline to offer promising therapeutic options for patients,” Poma said in a statement.

Under terms of the agreement, Molecular Template will undertake research responsibilities for the discovery of next-generation ETBs for multiple targets. BMS has already selected a target, but that was not disclosed by the companies in the announcement. If the ETBs are promising, BMS will have the option to develop and commercialize the assets.

BMS will make an up-front payment of \$70 million to MTEM. As the project moves forward, and other targets are selected, Molecular Templates could receive up to \$1.3 billion in milestone payments. The company would also receive tiered royalty payments on future sales.

Shares of MTEM jumped more than 24% on Thursday following the announcement of the collaboration. Share prices slipped some Friday morning, but are climbing again. The stock was up 1.5% as of 10 a.m.

Outside of its deal with BMS, in January, MTEM announced dosing would begin in the second quarter of this year in a newly-approved **Phase I study of MT-6402**, a next-generation ETB targeting PD-L1 that is enabled with MTEM's antigen seeding technology (AST). ETBs enabled with AST have dual mechanisms of action that include the enzymatic destruction of ribosomes and the delivery of viral class I antigens into the

targeted tumor to be processed and presented on its cell surface to induce an antigen-specific immune response, the company said. In preclinical studies, MT-6402 was found to specifically bind and kill both tumor and immune PD-L1 expressing cells.

Most Read Today

- [Abingworth's \\$582 Million Co-Development Fund Will Propel Late-Stage Trials](#)
- [Flagship Pioneering Announces Launch of mRNA Cousin eRNA with Laronde](#)
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From the Houston Business Journal:

<https://www.bizjournals.com/houston/news/2021/02/22/houston-oncology-co-raises-17m-for-clinical-trials.html>

Houston oncology co. Iterion Therapeutics raises \$17M for clinical trials

Feb 22, 2021, 1:41pm CST

Houston-based oncology firm Iterion Therapeutics Inc. raised a \$17 million funding round to push through clinical trials.

The round, an extension of the \$6 million Series B raise Iterion closed in late 2018, was led by Toronto, Canada-based Lumira Ventures. The funding round saw participation from returning investor Austin-based Santé Ventures as well as new investors Viva BioInnovator, GPG Ventures and Venture Investors, the company said.

Rahul Aras, CEO of Iterion, said the company plans to use proceeds from the capital raise to advance its lead clinical candidate, Tegavivint, through regulatory clinical trials. The drug candidate is currently undergoing a Phase 1/2a clinical trial to treat patients with desmoid tumors, which are rare, non-metastasizing sarcomas. Iterion has completed enrollment for its Phase 2a dose expansion clinical study of Tegavivint, Aras said.



COURTESY ITERION THERAPEUTICS

Rahul Aras, CEO of Iterion
Therapeutics

"This allows us to continue to follow the patients in that study and advance the desmoid program," Aras said. "Importantly, that now allows us to introduce Tegavivint in a number of new indications for which we have strong preclinical data."

Iterion currently employs 10 people and does not plan to significantly expand its team in connection with the capital raise. As the company continues to focus on clinical development, Iterion will look to add a couple of new employees to its headcount, mainly in clinical and product development, Aras said. Iterion will consider building out teams focused on commercialization further into the regulatory process, he said.

In addition to targeting desmoid tumors, Iterion aims to test Tegavivint's efficacy in treating patients with acute myeloid leukemia, non-small-cell lung cancer and pediatric cancer, Aras said. Each of these cancers are characterized by nuclear beta-catenin over-expression, according to the company. Tegavivint acts as a nuclear beta-catenin inhibitor, preventing the activation of the cancer genes while allowing the beta-catenin to resume its normal role in tissue function.

"We envision incredible potential therapeutic benefits associated with Tegavivint and are excited to support the Iterion team in its exploration of multiple clinical development opportunities for this potentially groundbreaking therapeutic," said Benjamin Rovinsky, managing director at Lumira Ventures.

Iterion is headquartered in TMCxi, a workspace to support and accelerate innovation in life sciences. TMCxi is located within the TMC Innovation Institute at 2450 Holcombe Blvd.

Chris Mathews

Reporter

Houston Business Journal



UT Health San Antonio gets \$6 million grant for DNA cancer research from state agency

By Laura Garcia - San Antonio Express-News

UT Health San Antonio has received a \$6 million academic research grant from a state-funded program that invests billions in cancer-fighting efforts.

The major grant from the Cancer Prevention and Research Institute of Texas or CPRIT swayed Alexander Mazin, a senior biochemist and cancer biologist at Drexel University College of Medicine in Philadelphia, to bring his lab and work on DNA repair to the Mays Cancer Center in the South Texas Medical Center.

Mazin accepted a tenured professor position teaching biochemistry at the Joe R. and Teresa Lozano Long School of Medicine and will be a contributor to the center's development and progression program studying cancer drugs.

The cancer center houses UT Health San Antonio MD Anderson, which is one of four National Cancer Institute-designated Cancer Centers in Texas and treats more than 30,000 patients each year.

This is the school's third CPRIT Recruitment of Established Investigator Award since 2018, which helped the university and Mays Cancer Center attract DNA repair expert Patrick Sung from Yale University, and breast cancer and radiation biology researcher Dr. David Gius from Northwestern University.

Dr. Ruben Mesa, executive director of the Mays Cancer Center, said the CPRIT recruitment grant was crucial for the internationally acclaimed research team as it seeks additional funding to study inherited cancer genes and develop drug therapies.

"We have been building a world-class team focusing on the issue of DNA repair," he said. "This is really one of the main drivers of cancer and has been one of the more effective approaches in trying to target cancers."

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<https://www.expressnews.com/news/local/article/UT-Health-San-Antonio-gets-6-million-grant-for-15985067.php>

Impact of Running Reaches Marrow to Spark Bone Growth in Mice

A study offers a new explanation for how exercise strengthens bones and the immune system.



Emma Yasinski

Mar 2, 2021

Mechanical forces from running and walking that are transmitted along blood vessels in marrow induce the growth of new bone and immune cells in mice, scientists reported in [Nature](#) on February 24. The study is the first to demonstrate that mechanical forces can influence cellular growth and differentiation in the bone marrow, according to the authors, and provides a possible new explanation for how exercise strengthens bones and the immune system.

It's well known that aging weakens bones and [running can help strengthen](#) them.

"The way that's understood to work is the mechanical forces are thought to act on the bone itself. And the soft bone marrow inside your bones is going to be insulated from those mechanical forces," says Sean Morrison, the director of the Children's Medical Center Research Institute at UT Southwestern and the senior author of the new study. His latest work counters the insulation theory and shows that arteriolar blood vessels that go through the bone surface to the marrow transmit movement-induced mechanical forces and thereby stimulate the proliferation of bone- and immune-cell precursors.

Siddaraju Boregowda, a stem cell biologist at the Scripps Research Institute who was not involved in the work, tells *The Scientist* in an email that the study is "elegant" and that the researchers "teased out the complexity" of how environmental factors such as exercise influence cell growth in the bone marrow.

The latest study connects the dots between two discoveries Morrison's team had made in recent years. The first was of a population of cells surrounding the blood vessels that travel through the bone to the bone marrow; it wasn't initially clear what these cells were doing or how they were interacting with other cells. The other discovery was of a

ABOVE: Deep imaging of bone marrow in a mouse femur showing that ostelectin-expressing cells (red) are around arterioles (white) but not sinusoids (green), a different type of blood vessel in the bone marrow.

CHILDREN'S MEDICAL CENTER
RESEARCH INSTITUTE AT UT
SOUTHWESTERN

growth factor, which they named **ostelectin**, that helps maintain bone mass in adult mice by stimulating the formation of bone cells in the marrow.

The researchers weren't sure how ostelectin was produced, so in the latest study, Bo Shen, a postdoc in Morrison's lab, used a chemical tag to figure out which cells were producing the growth factor. It turned out they were the cells they'd previously discovered around the arteriolar blood vessels.

Knowing that bones weaken with age and that both running and ostelectin seem to protect them, Shen and his team wondered if the growth factor was responsible for the exercise benefit. They found that older mice that ran on a wheel produced more ostelectin and more new bone cells compared with older mice that didn't run. Additionally, the researchers found that as the bone cells grew, they secreted growth factors that encouraged the formation of immune cells, which improved the animals' ability to fight off bacterial infections.

To see what it was about exercise that stimulated the cells to make the growth factor, the team genetically modified mice so their ostelectin-producing cells would no longer make a receptor, Piezo1, that is known to respond to mechanical forces such as the physical impact of running. With the receptor gone specifically from those cells, the bone and immune cells no longer proliferated in response to exercise.

"The most exciting thing that we found was that these cells around the arteriolar are mechanically regulated—they require mechanical stimulation in order to be maintained," says Morrison.

David Ferguson, a physiologist at Michigan State University who was not involved in the study, calls the work "massive, impressive, and really well done." He says his own lab, which studies the effects of exercise on growth and development in mice, will benefit from the results. The authors, he adds, "provided a very nice path for us to look at certain types of cells and environmental factors."

See "**Neural Connections Bolstered in Monkeys That Lift Weights**"

The results shed light on so-called stem cell niches—specialized environments in the bone marrow that are controlled by growth factors. Very few of the bone marrow's niches have been studied in depth. Morrison says he was

I don't think there's any stem cell niche in any mammalian tissue that has so far been shown to be mechanically regulated.

—Sean Morrison, UT Southwestern

shocked to find that mechanical forces from exercise could play a role in maintaining their conditions.

“I don’t think there’s any stem cell niche in any mammalian tissue that has so far been shown to be mechanically regulated,” says Morrison. “This opens the wider question of whether mechanical stimulation is necessary more often than we thought [to regulate niches].”

B. Shen et al., “A mechanosensitive peri-arteriolar niche for osteogenesis and lymphopoiesis,” *Nature*, doi:10.1038/s41586-021-03298-5, 2021.

Keywords:

blood vessels, bone, exercise, growth factor, **immunology**, mechanical force, News, osteolectin, **physiology**

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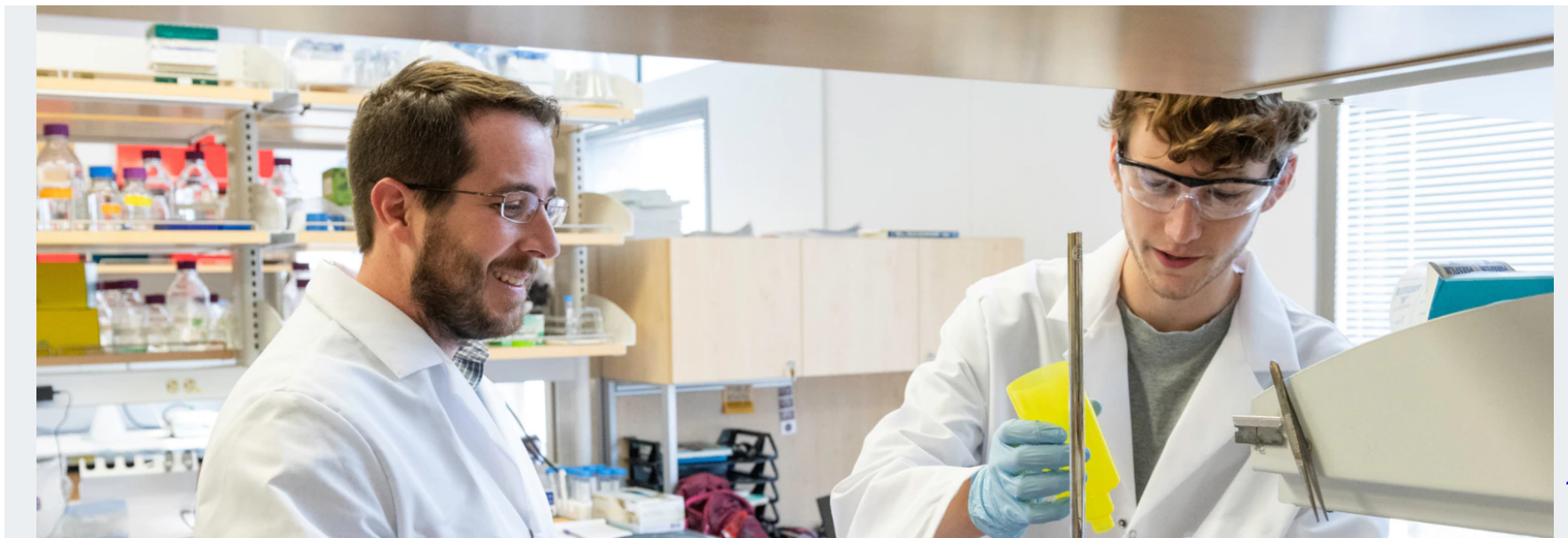
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Breakthrough research at UT Austin is protecting the world against COVID-19

Jason McLellan lab's study of the coronavirus's spike protein has been instrumental in creating vaccines.



15-14



McLellan, an associate professor of molecular biosciences at UT, leads a research team that has helped other scientists understand the nature of the coronavirus. (Courtesy of UT Austin)



By [Belo Content Studio](#) and Sponsored by UT Austin

11:33 AM on Mar 12, 2021



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In the past year, scientists around the world have worked to respond quickly to the COVID-19 pandemic. The University of Texas at Austin is among the top universities in the nation for pandemic research and has played a crucial role in protecting against the virus. Along with researchers at the National Institutes of Health, UT's **Jason McLellan** and his team have made a number of key discoveries, which major drug companies have used to develop vaccines.

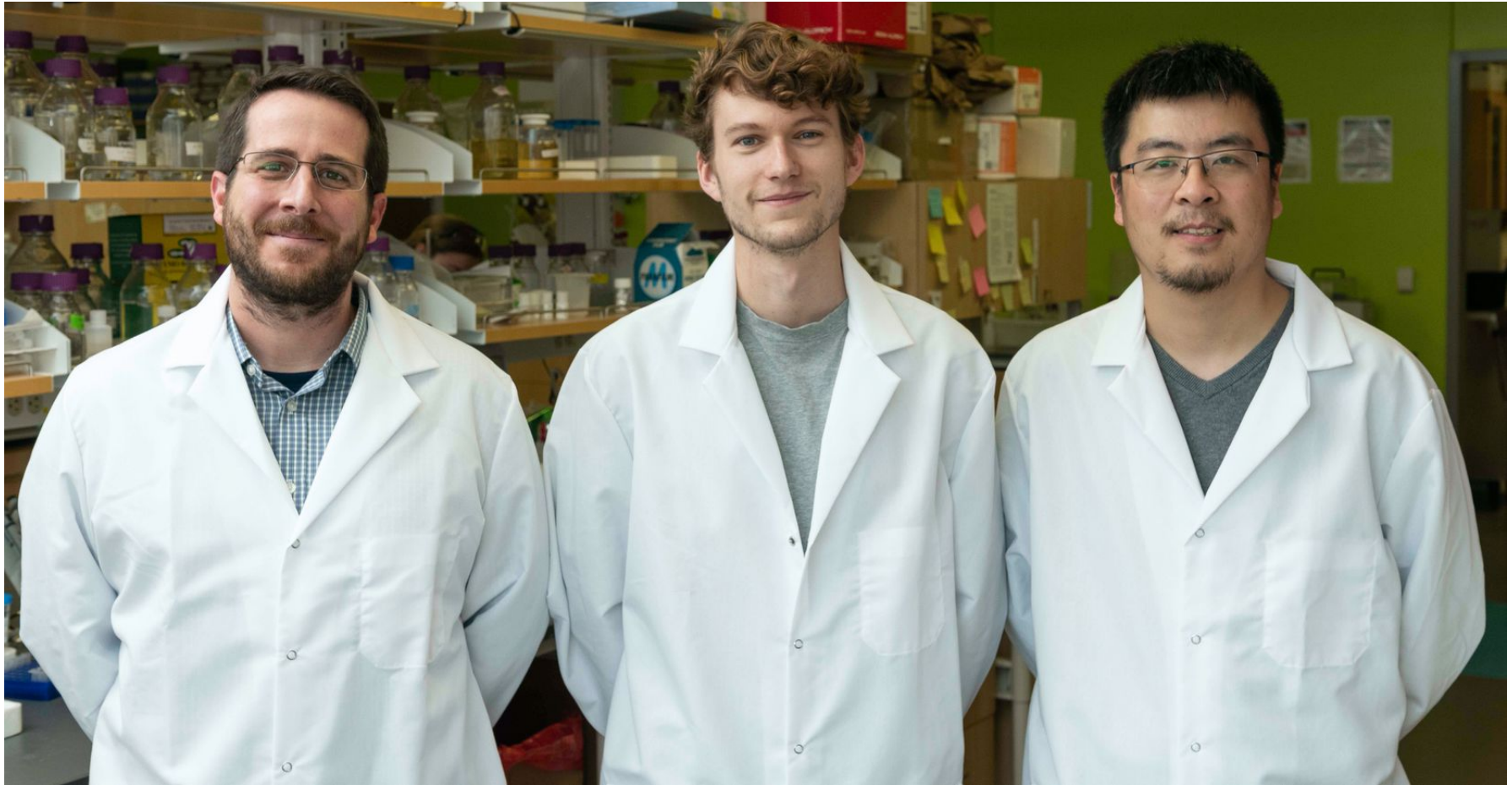
McLellan, an associate professor of molecular biosciences, has focused on the structure of viruses, including the spike protein that makes up the outer surface of the coronavirus. He and his team observed that these spike proteins change their shape to attach to cells, subsequently infecting them. As COVID-19 emerged, McLellan's

15-15

team also created the first 3D atomic scale map featuring the spike protein. This map has helped other scientists understand the nature of the virus.

The team's findings have led to **the fastest vaccine development in history**. The spike protein is now being incorporated in many vaccines, including the Pfizer-BioNTech and Moderna vaccines, which are 95% effective.

McLellan's earlier research with other coronaviruses aided in the rapid production of COVID-19 vaccines. In 2016, a llama named Winter played an important part in McLellan's coronavirus research while he was working with scientists at Ghent University in Belgium. For over a month and a half, Winter was injected with stabilized spike proteins from SARS-CoV-1 and MERS-CoV. Researchers then collected a blood sample and isolated antibodies that bound to each version of the spike protein. This helped McLellan's team recognize that when the body senses the spike protein as a potential threat, it develops antibodies to prevent infection.



Key discoveries from a team of researchers at UT has led to the fastest vaccine development in history. (Courtesy of UT Austin)

Coronavirus research has made progress thanks to UT's access to technology and equipment funded by the Cancer Prevention and Research Institute of Texas. **The Sauer Laboratory for Structural Biology's** ultra-low-temperature electron microscopes and the Texas Advanced Computing Center's **Frontera supercomputer** continue to help researchers gain a better understanding of the disease and treatment.

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15-17

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The Texas Department of State Health Services (DSHS) has designated UT as a **vaccine hub** for Texas. The university will be allocated additional supplies of vaccine from the state and is administering it in two doses to **Phase 1A** and **Phase 1B** individuals in accordance with federal and state guidance to keep the university community — and greater Austin — safe from COVID-19. Vaccinations for the rest of the population will be available at a later date as determined by DSHS. UT's proactive community testing, case information and other comprehensive information can be found at **Protect Texas Together**.

McLellan said he is “thrilled” to see that the vaccine, made possible because of his dedicated work, is being distributed across the nation.

“With Pfizer-BioNTech and Moderna announcing 95 percent efficacy, it’s really ecstatic, and it’s great for the world,” he said.

15-18

AI, digital health feature in latest batch of FDA breakthrough device designations

Published May 5, 2021

By Nick Paul Taylor
Contributor

FDA has issued another batch of breakthrough device designations. The latest crop sees the agency grant regulatory privileges to a set of AI and digital health companies including **Koios Medical** and **Nēsos**.

Koios landed breakthrough status for AI software designed to enable the early detection of breast and thyroid cancer. The software analyzes breast and thyroid ultrasound images to help radiologists determine if a biopsy is needed. Koios is pitching the system as a way to both prevent unnecessary biopsies of benign tissues and improve cancer detection rates.

Perimeter Medical Imaging AI also secured breakthrough designation for an AI-enabled approach to imaging. FDA awarded the status to Perimeter's Optical Coherence Tomography Imaging System coupled with ImgAssist AI. The imaging system, which is already cleared by FDA in the evaluation of excised human tissue microstructure, is designed to provide real-time, ultra-high-resolution images. Perimeter is incorporating AI to help surgeons tell if cancer is still present after surgical excision.

Two other digital-focused medtechs recently received breakthrough designations. FDA awarded the status to Nēsos' prescription digital therapeutic for rheumatoid arthritis. The device consists of earbuds that deliver electrical signals to modulate neurological pathways and, in doing so, rewire the immune system to reduce the severity of rheumatoid arthritis.

Digital health company **Implandata Ophthalmic Products** received FDA breakthrough status for its Eyemate system. The system consists of an implantable micro sensor designed to facilitate the continual remote monitoring and management of glaucoma patients. Implandata is framing the device as a way for physicians to keep tabs on the glaucoma status of their patients between office visits, which it says typically happen two to four times a year.

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